Message

From: Mone, Michael [/O=CAH/OU=CARDINAL HEALTH/CN=RECIPIENTS/CN=MICHAEL.MONE]
Sent: 10/1/2008 2:59:15 PM
To: Anderson, Chris (QRA) [chris.anderson@cardinalhealth.com]
Subject: RE: Anti-Divesrion CBT - Distribution Center Employees
Attachments: Anti_Diversion_v8_020508MAM.ppt

Chris:

I made a few changes to the slides as some information has changed a bit. I like the training, I just wonder whether the correct website addresses for the questionnaires and other electronic enhancements, e.g. email boxes would be valuable being included?

Your thoughts

Michael

From: Anderson, Chris (QRA)
Sent: Tuesday, September 30, 2008 4:38 PM
To: Anderson, Chris (QRA); Mone, Michael
Subject: RE: Anti-Divesrion CBT - Distribution Center Employees

Michael,

This is my weekly nagging (yes it's been a week) about the Ant-Diversion CBT. This is part of my SOM Workplan, so the nagging won't stop (although it may switch to begging and bribery through dinner offers).

As always, I eagerly await your response.

Thanks!

Chris

Chris J. Anderson
Director, Operational Excellence
Quality Systems (QRA)
Healthcare Supply Chain Services
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614-652-9675 (fax)
chris.anderson@cardinalhealth.com
anderson, chris (QRA) in Outlook

From: Anderson, Chris (QRA)
Sent: Tuesday, September 23, 2008 1:35 PM
To: Mone, Michael
Subject: Anti-Divesrion CBT - Distribution Center Employees

Michael,

I have attached two outlines developed by our web-based instructional designers that were created from your slides (Anti_Diversion_v8_020508.ppt). We broke this out into two modules because of the size. The team has begun to work on storyboards for the web-based CBT modules.

If you could squeeze in a review of these into your busy schedule, it would be greatly appreciated! The next step would be for you to review the storyboards and then the final CBT in Flash.

Also, the instructional designer has three questions from your aforementioned slide deck:

1. Slide 59 (attached) refers to IT Component (I can answer about the SOM Status, but is the scope of your slide deeper?)
    a. Does the tool already exist?
    b. What is it called?
    c. Who uses it?
2. Thresholds (pg 60)
    a. What is class of trade?
    b. What are dispensing characteristics?
    c. What does "Non-discloseable - capture intent" mean?
3. QRA evaluation process (pg 67)
    a. When are these reviews, questionnaires, and site visits necessary?
    b. Do they only happen when a suspicious order is identified?

Again, you help is greatly appreciated! And remember the meal I bought you ☺

Thanks!

Chris

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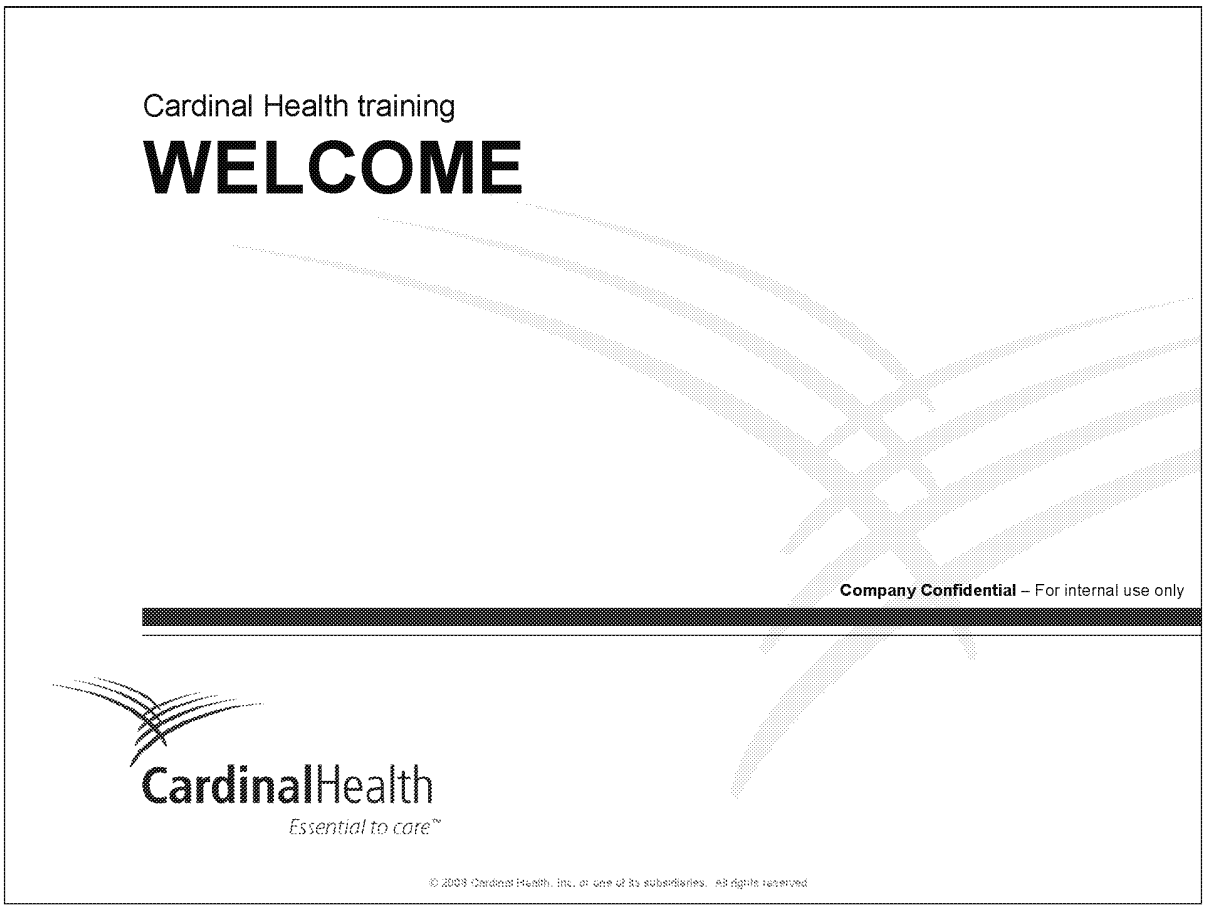
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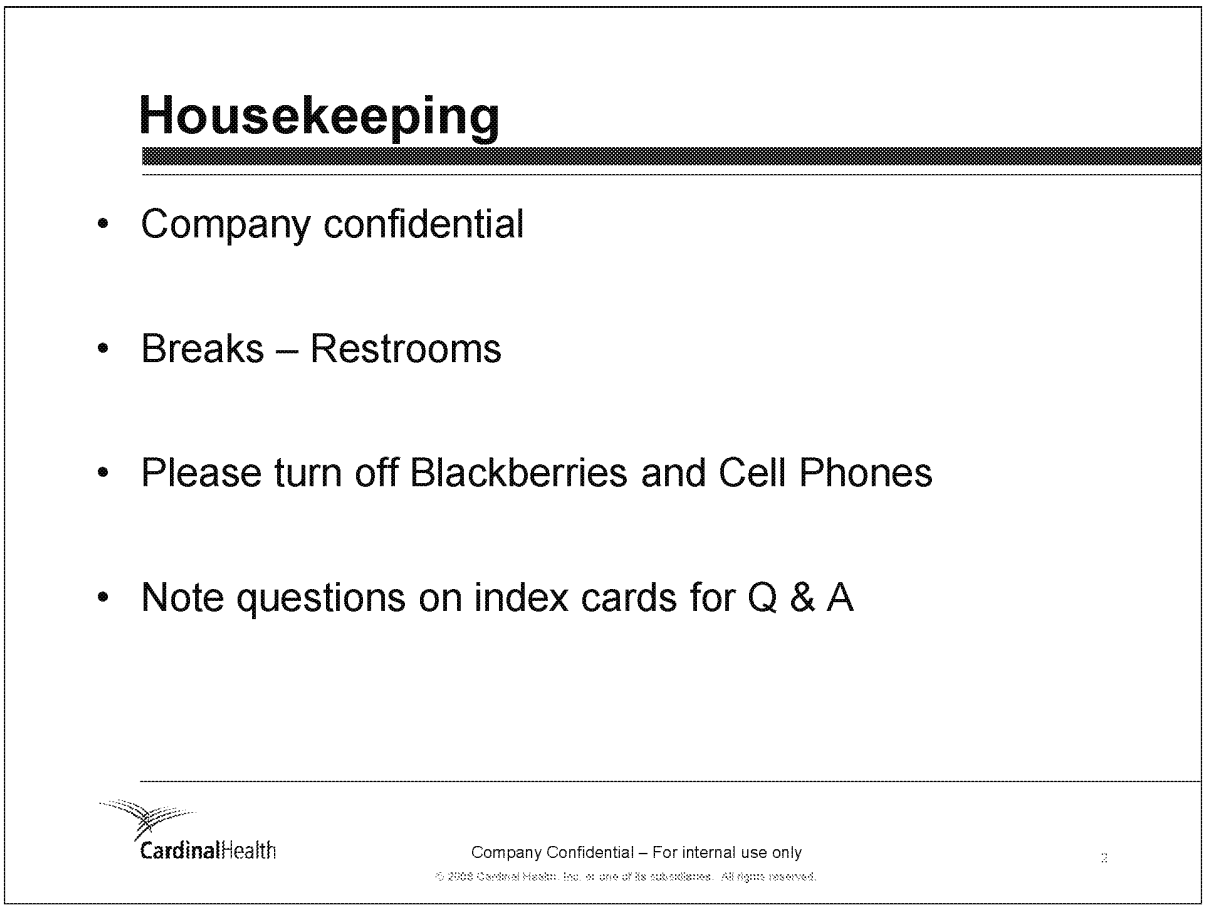
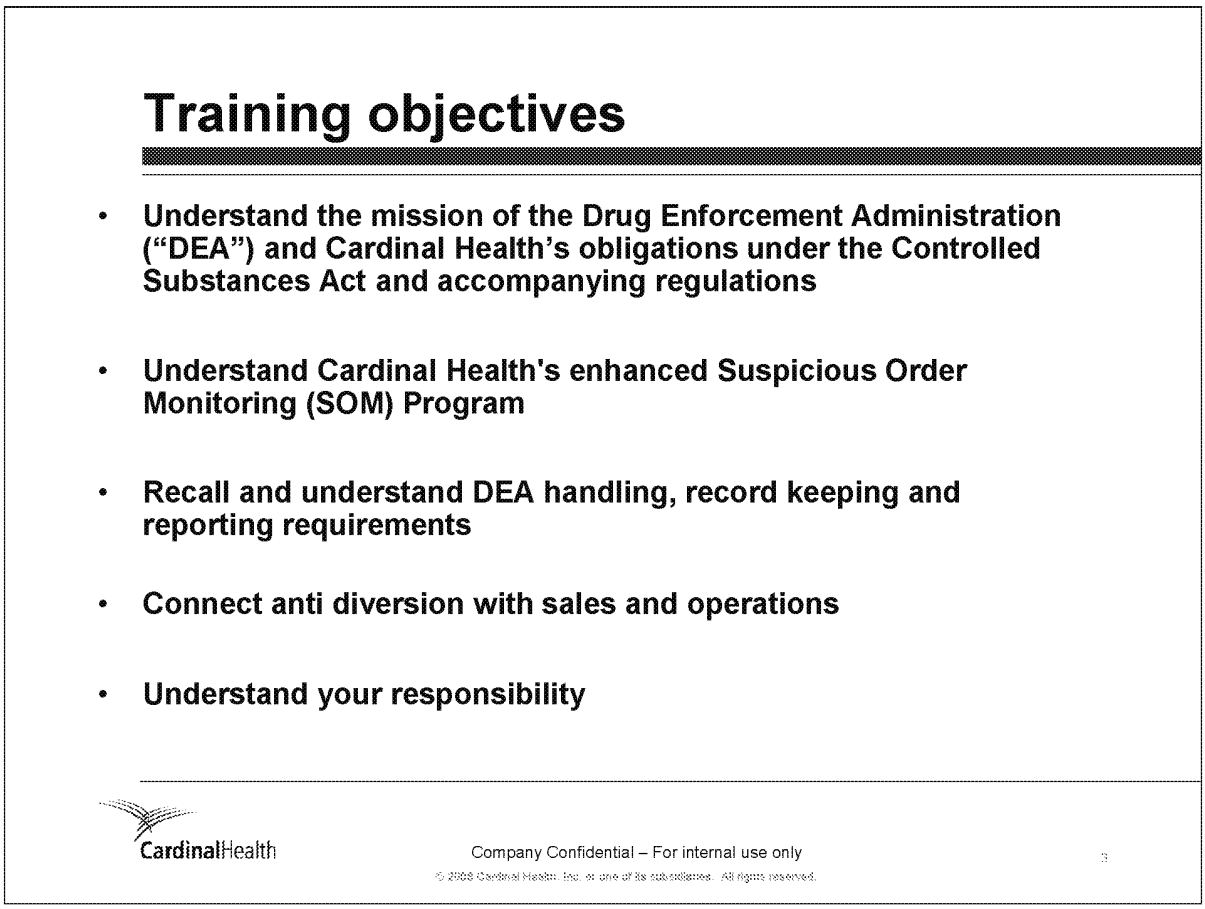


Most questions will be answered by the content. Confirm that to everyone.

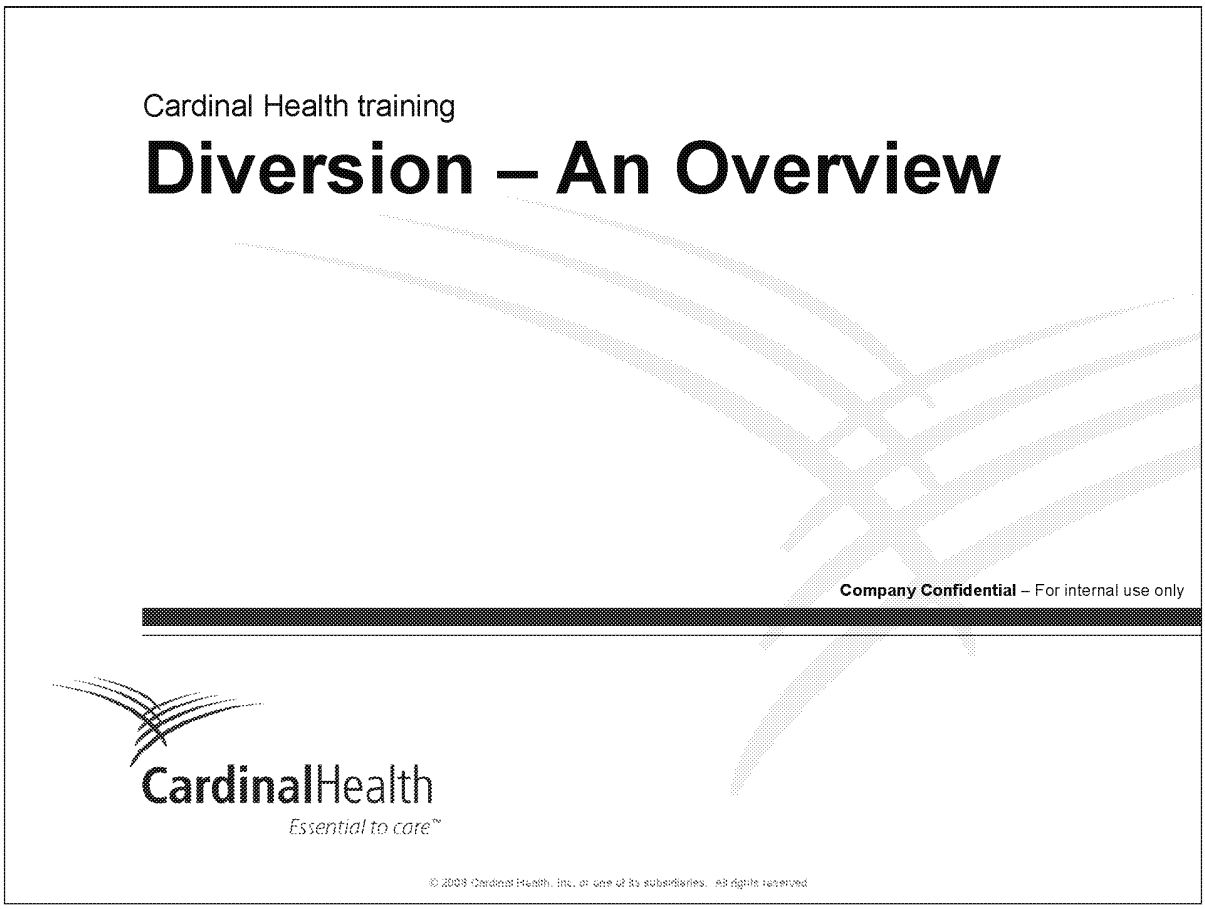
Encourage the use of the index cards to make notes.



Objective: Set the objectives

Timing: 2 min

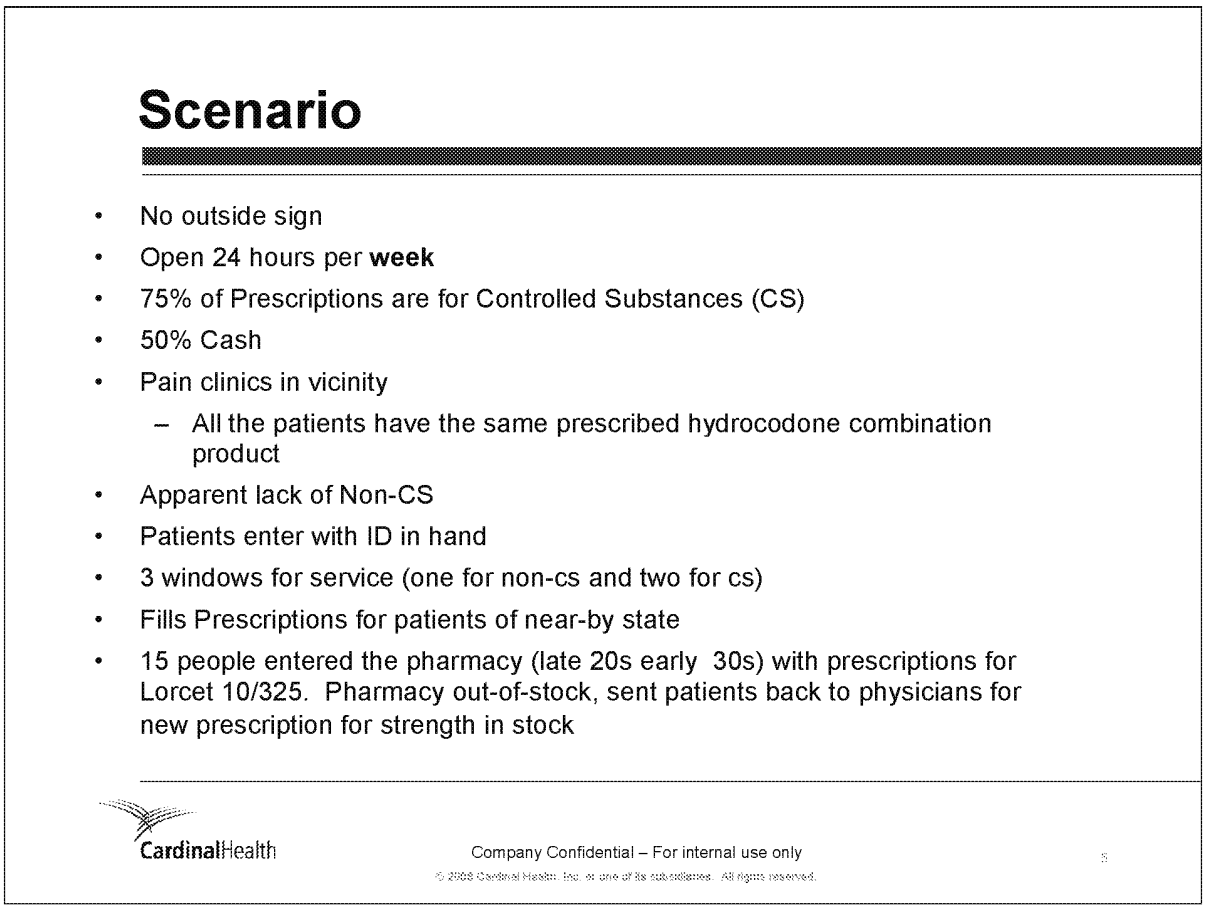
Notes Over the last few months we have made begun to focus even more on our anti diversion commitment. In order to make sure that we are consistent in our understanding of the process we have been tasked with sharing this training with you. Some things will be familiar to you. Our know your customer program is familiar to sales and some of the reporting and security processes are familiar to operations.
So what are we doing here today
Understand DEA mission
Understand Cardinal Health's enhanced SOM program
Recall handling and record keeping requirments
And finally to connect the antidiversion efforts of sales and operations to make a combined front against this societal problem.



Objective: Begin

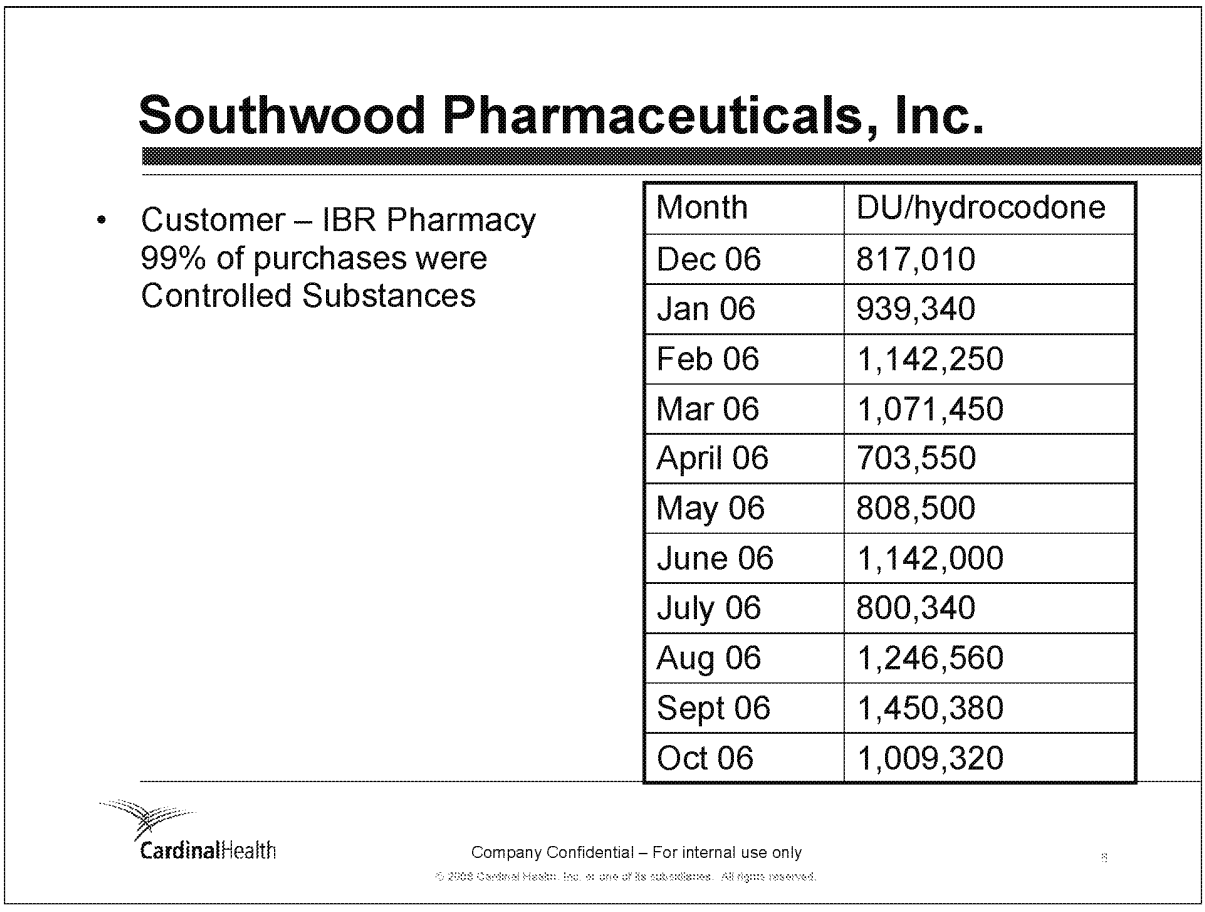
Timing:

Notes:



Let's try a scenario.
You see a pharmacy as described here.
Yes , that DOES say 24 hours a WEEK.
50% cash. Is that a bad thing? You see the 3 windows and there is a line at the two CS windows and cobwebs at the non CS counter.
Is this a pharmacy we would want to be doing business with? Probably an easy one to decide on. The point of the exercise is that we need to be constantly gathering information and making observations about what is happening within the pharmacy.

Transition: Now that we've looked at this scenario let's talk about the type of transactions that have put the industry in a heightened sense of responsibility.



Southwood Pharmaceuticals, Inc.

- Customer – IBR Pharmacy
  99% of purchases were
  Controlled Substances

Month	DU/hydrocodone
Dec 06	817,010
Jan 06	939,340
Feb 06	1,142,250
Mar 06	1,071,450
April 06	703,550
May 06	808,500
June 06	1,142,000
July 06	800,340
Aug 06	1,246,560
Sept 06	1,450,380
Oct 06	1,009,320

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Objective: Illustrate the diversion crisis

Timing: 2 min

Notes: Southwood Pharma. A distributor in California
This shows the transactions for one pharmacy (the name is fiction but the numbers are not) over an 11 month period. This is in dosage units. Pills. Has everyone here seen what a bottle of 1000 hydrocodone looks like? In December this customer got 800 of them!!!

Transition: But wait, there's MORE.

Southwood Pharmaceuticals, Inc. - cont'd

- Plato Pharmacy – Admitted Internet pharmacy – 100% controlled substance sales

Month	DU
Dec 05	346,140
Jan 06	859,860
Feb 06	0
Mar 06	912,190
April 06	76,190
May 06	212,000
June 06	442,800
July 06	94,000
Aug 06	506,430
Sep 06	695,800
October 06	537,900
Nov 06	2,111,800

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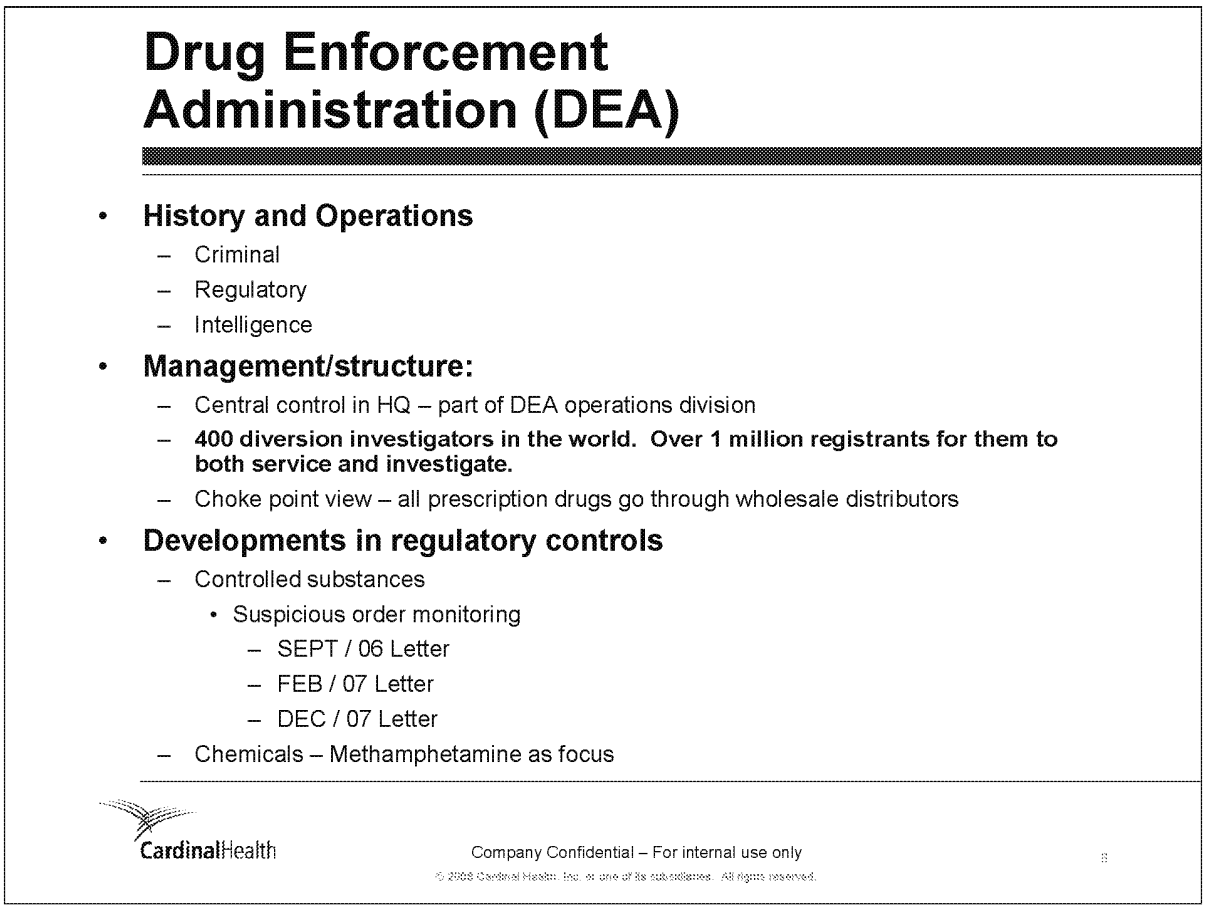
Objective: Underscore diverision issue

Timing: 1 min

Notes: Here is another customer. Admitted internet pharmacy. 100% control sales.
Southwood's argument was that they were shipping to a company that was duly licensed by the federal and state government.
Apparently the DEA did not agree with the company's argument.
In November of 2006 this company shipped over 2 million does to patients that had no real doctor patient relationship.
THIS is what we are all charged with preventing.
Transition: Now that we have set the stage let's move to the DEA.



Objective: Discuss the set up of the agency

Timing: 5 min

Notes: DEA has three units with only 400 diversion investigators
Over 1 million registrants –
the vast majority are physicians with the balance manufacturers, distributors, pharmacies, researchers, analytical labs, hospitals

Distributors are viewed as a choke point for the supply chain. The agency may not have total visibility to pharmacies but the distributor DOES.

The DEA has increased their enforcement and regulatory investigations against distributors, manufacturers, pharmacies and physicians. DEA has three operational elements and work forces which are dedicated to criminal, regulatory and intelligence.

DEA Guidance – Feb/Sept 07

- Reporting suspicious orders to DEA does **NOT** relieve a distributor of the responsibility to maintain effective controls to prevent diversion.
- DEA official told this to industry conference in September 2007 ("If you report suspicious orders, yet fill them .... You are **failing** to maintain effective controls to prevent diversion").
- DEA provided warning letter to all distributors in early 2007.

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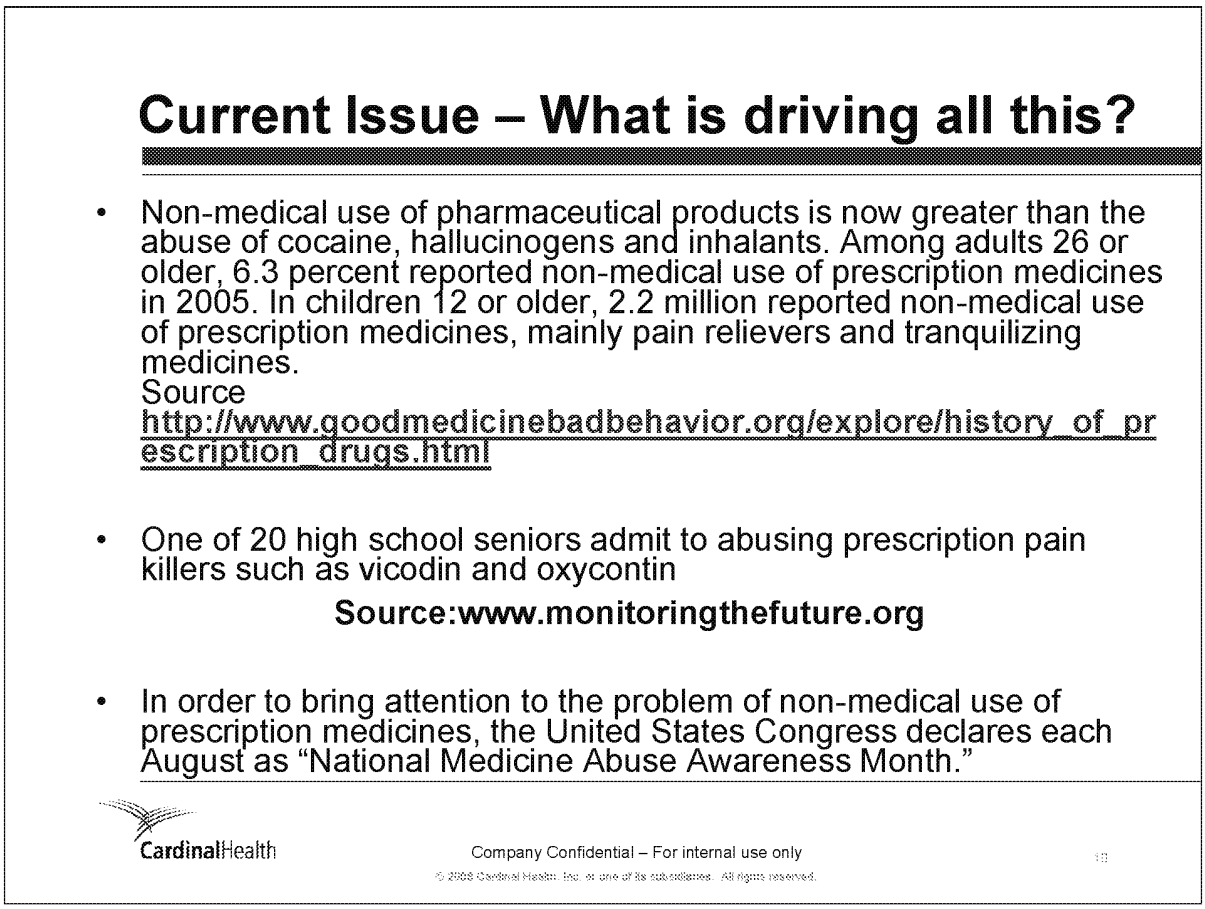
Objective: Discuss the timeline of DEA guidance for preventing diversion

Timing: 5 min

Notes: In 2005 the DEA starting educating distributors about the growing incidence of prescription drug abuse.
These discussions were around the law, trends and problem customers.
DEA emphasized their interpretation of what makes a valid prescription – a face to face relationship between patient and physician – and their concern over internet pharmacy because those do NOT meet that criteria.
In Feb and Sept 07 the DEA clarified that reporting does NOT relieve the distributor of the responsibility of effective control AND if you report but continue to ship you are FAILING to maintain effective control to prevent diversion.

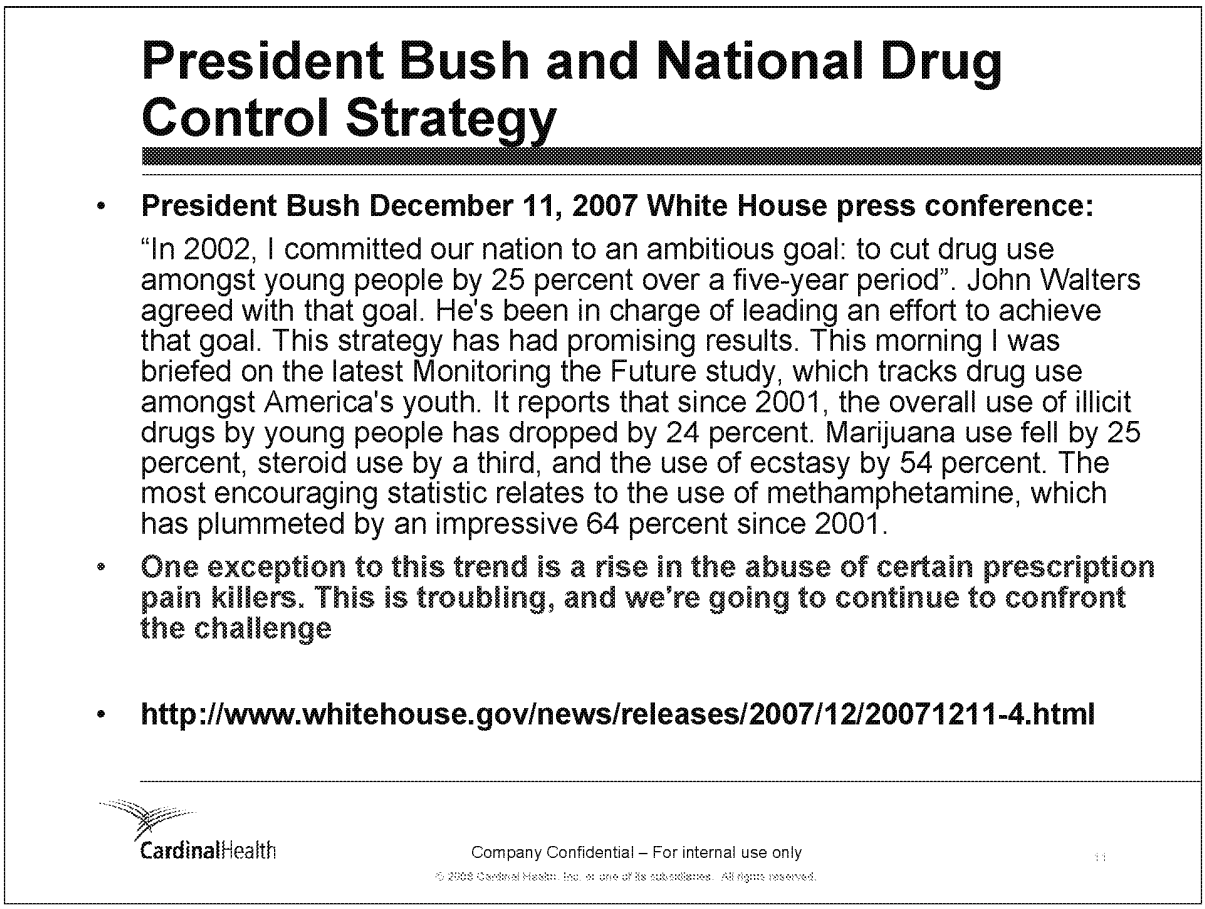
This is how the industry finds itself in the situation its in today. We all thought we were doing good enough .. But we weren't.



Objective: Discuss drug abuse statistics

Timing: 2 min

Notes: Prescription drug abuse is rising across all age groups. Exceeding cocaine, hallucinogens and inhalants. One out of 20 high school seniors admit to abusing pain killers like vicodin and oxycontin.



Objective: Underscore the level of visibility for this issue

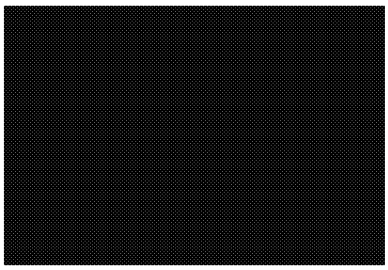
Timing: 5 min

Notes: In 2002 President Bush committed to reducing drug use among young people by 25% over a 5 year period. Highlight the successes in reduction of illicit drugs.
Contrast that to the final statement that there is a rise in abuse of 'certain' prescription pain killers and that challenge will be confronted.

How dangerous is it to abuse prescription drugs?

- Perception of safety because it is medicine
- Less of a stigma, because of the ease of access
- No need to go to dark alleys

But....let's see what is happening in the world.



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Objective: Illustrate the difference between prescription and illicit drugs

Timing: 5 min

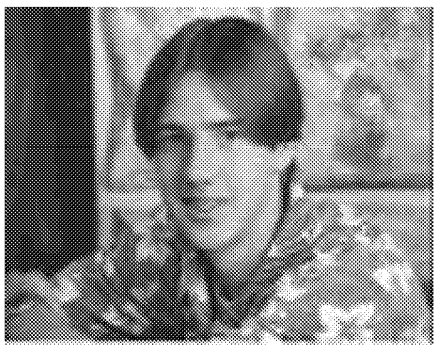
Notes: Perception that it is medicine so should not really be 'bad'.

Show the super bowl commercials

Comment after the commercial/transition: How does that make you feel? Not what you think but how you feel? Responsible is a good word to pick up on. Makes you want to do more to make sure this doesn't happen. Remember when the kid says 'this yellow one was for my postpartum depression'? That was probably Zoloft. That particular item is not a controlled drug but is an anti-depressant. That class of anti-dipressants now has a black box warning on every bottle. This warning indicates much higher incidence of suicidal thoughts and attempts by teenagers taking this medication and they should be monitored closely. This is another way the misuse of prescription drugs can negatively impact society. Let's do what we can to continue to monitor and educate.

Ryan Haight

Ryan Thomas Haight overdosed and died on February 12, 2001 on narcotics that he had easily purchased on the Internet. A medical doctor on the Internet that he never saw prescribed them, an Internet pharmacy mailed them to his home. He was only 17 when he purchased them, he was only 18 when he died. It is too simple to get dangerous prescription drugs on the Internet. It is too easy for our youths to get information about drugs and to find out how and where to get them.



http://www.ryanscause.org/index.html

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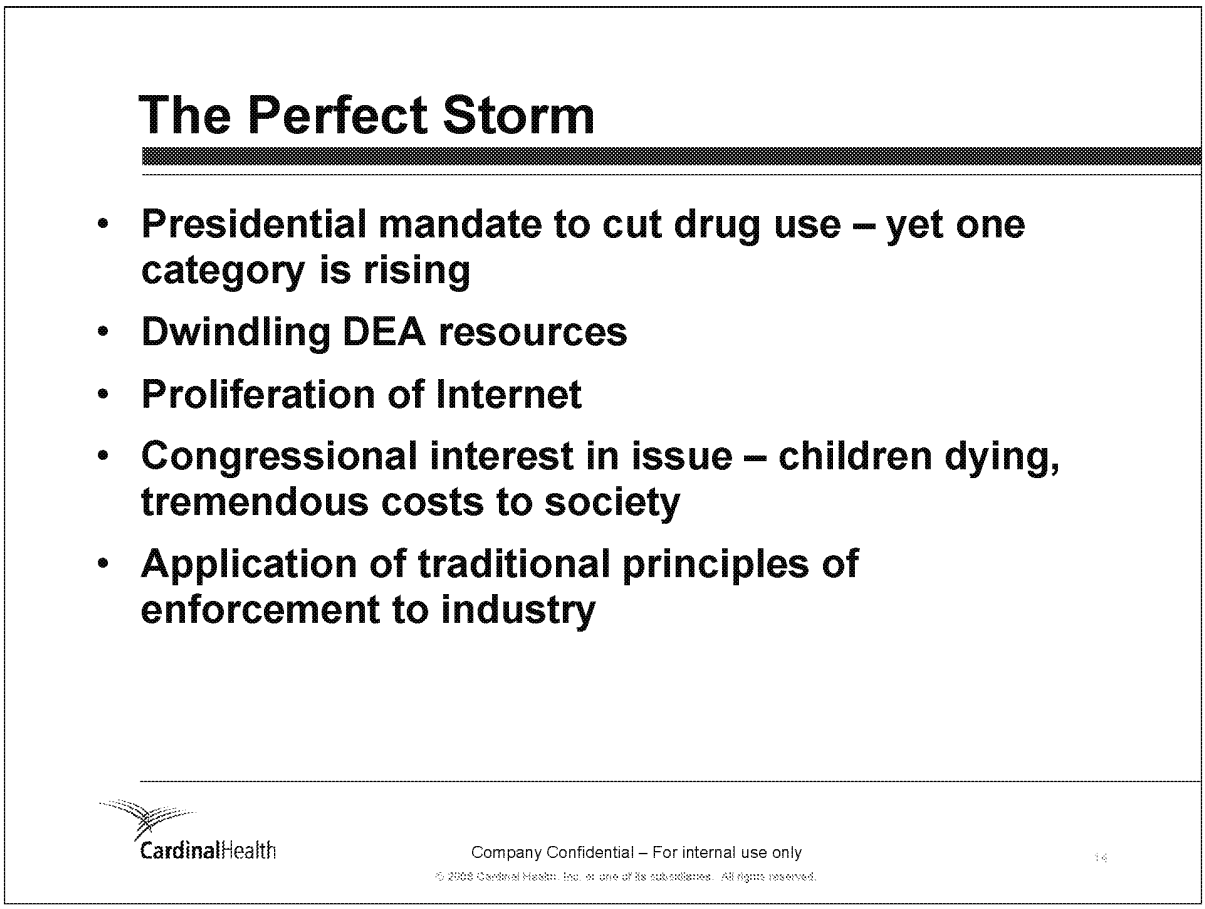
13

Objective: Put a face to the statistics

Timing: 2 min

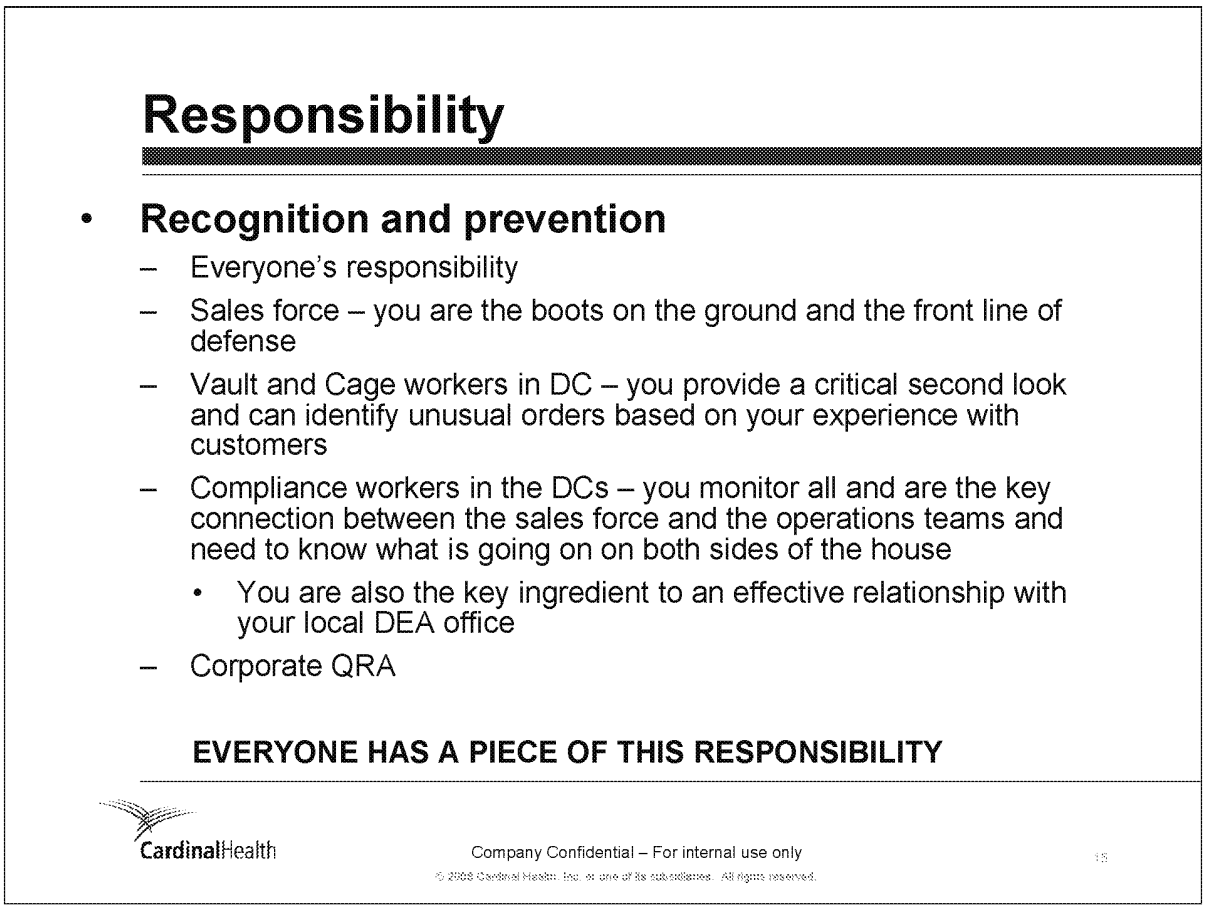
Notes: Go through the timeline and players



Objective: Sum up the circumstances

Timing: 5 min

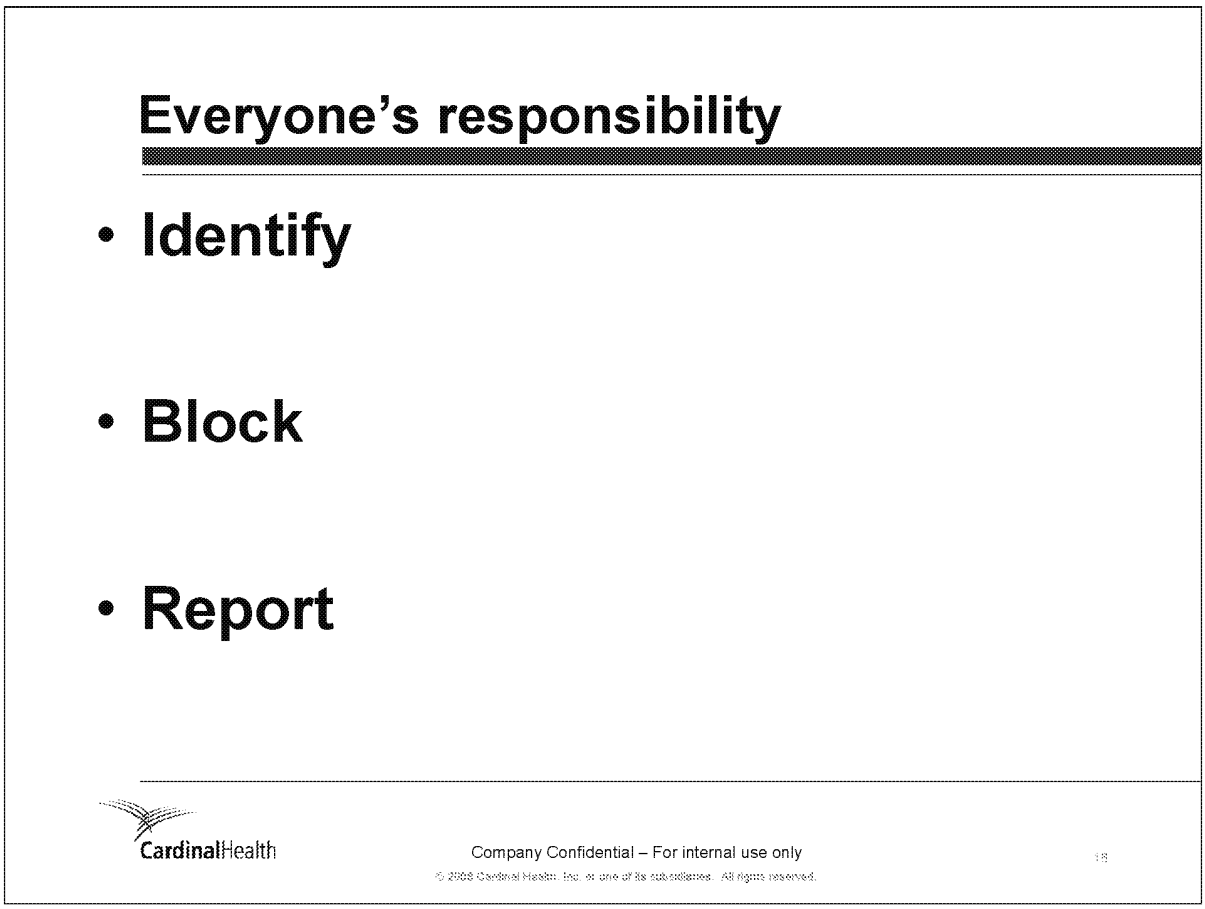
Notes: President mandates a reduction in drug abuse – that is a success – except for this one category. This one nail waiting for the governmental hammer.
DEA resources are shrinking. Remember 400 agents for well over a million registrants.
Internet commerce makes life convenient but the darker side is that it is much harder to control and police and thereby becomes a pipeline for diversion.
The number of deaths from prescription drug overdose makes it a matter of interest for Congress and higher profile issue.
The agency is looking at the industry and using traditional principles of enforcement. Seeing diverters as filling prescriptions illegally and considering a willingness to continue to ship to diverters as an enabling act.



Objective: Underscoring responsibility

Timing: 5 min

Notes: emphasize it is EVERYONE'S responsibility. Ask the room 'Who's responsibility is recognition and prevention?' – when they answer everyone's have them repeat.. But louder.
Make comment on each of the groups listed.
Sales – eye and ears
Vault and Cage – see what normal looks like and can try to identify orders that 'don't look right'.
Compliance/QRA – monitor internally and externally. The bridge between the field and the DC
Corp QRA – monitoring thresholds and policies.
Transition: What are the three words that encapsulate our responsibility?



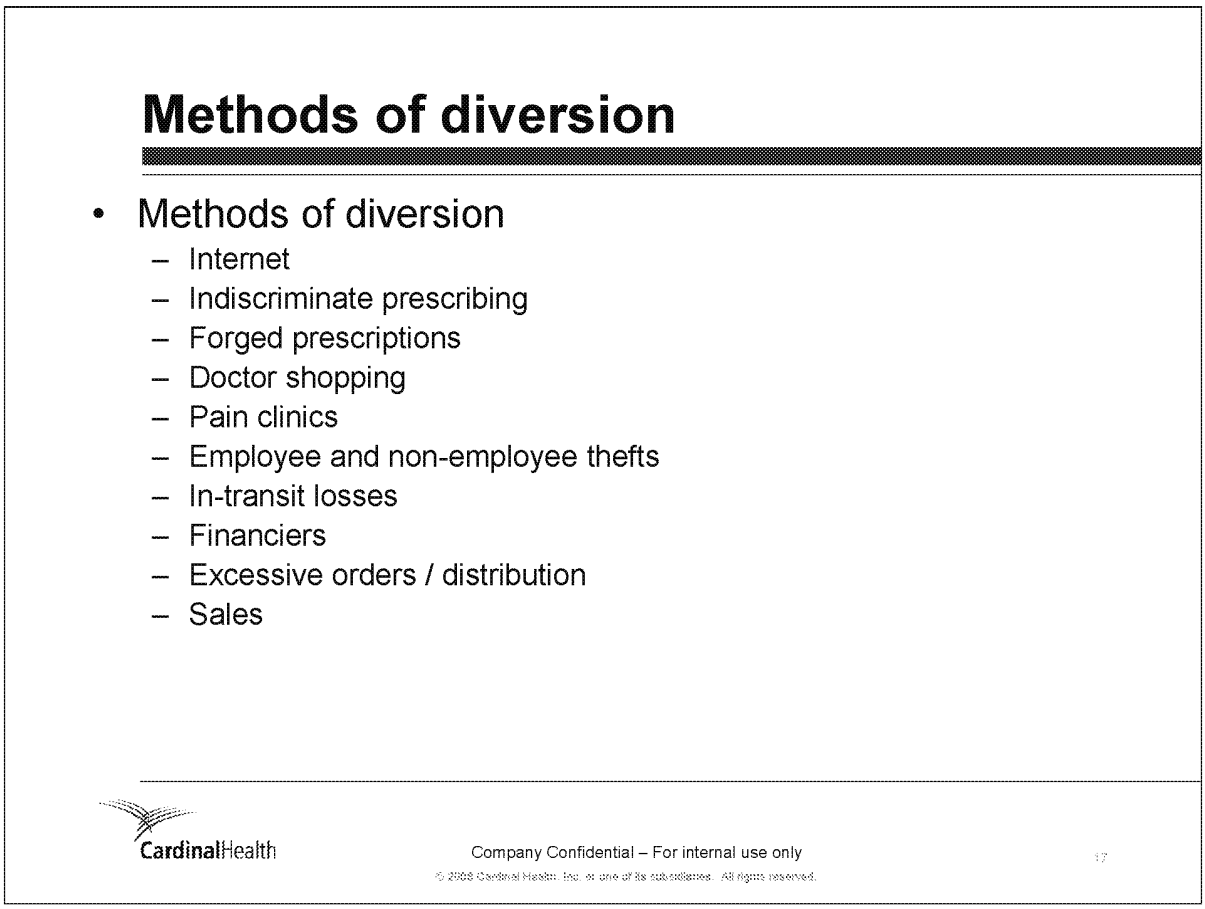
Objective: Introduce the concept

Timing: 2 min

Notes:
Identify suspicious orders/activities
Block the order and assess
Report suspicious orders to regulatory agency (DEA/state board)

Now everyone say it all together IDENTIFY BLOCK REPORT

Transition: Let's talk about what some of the substances we need to identify block and report actually are.

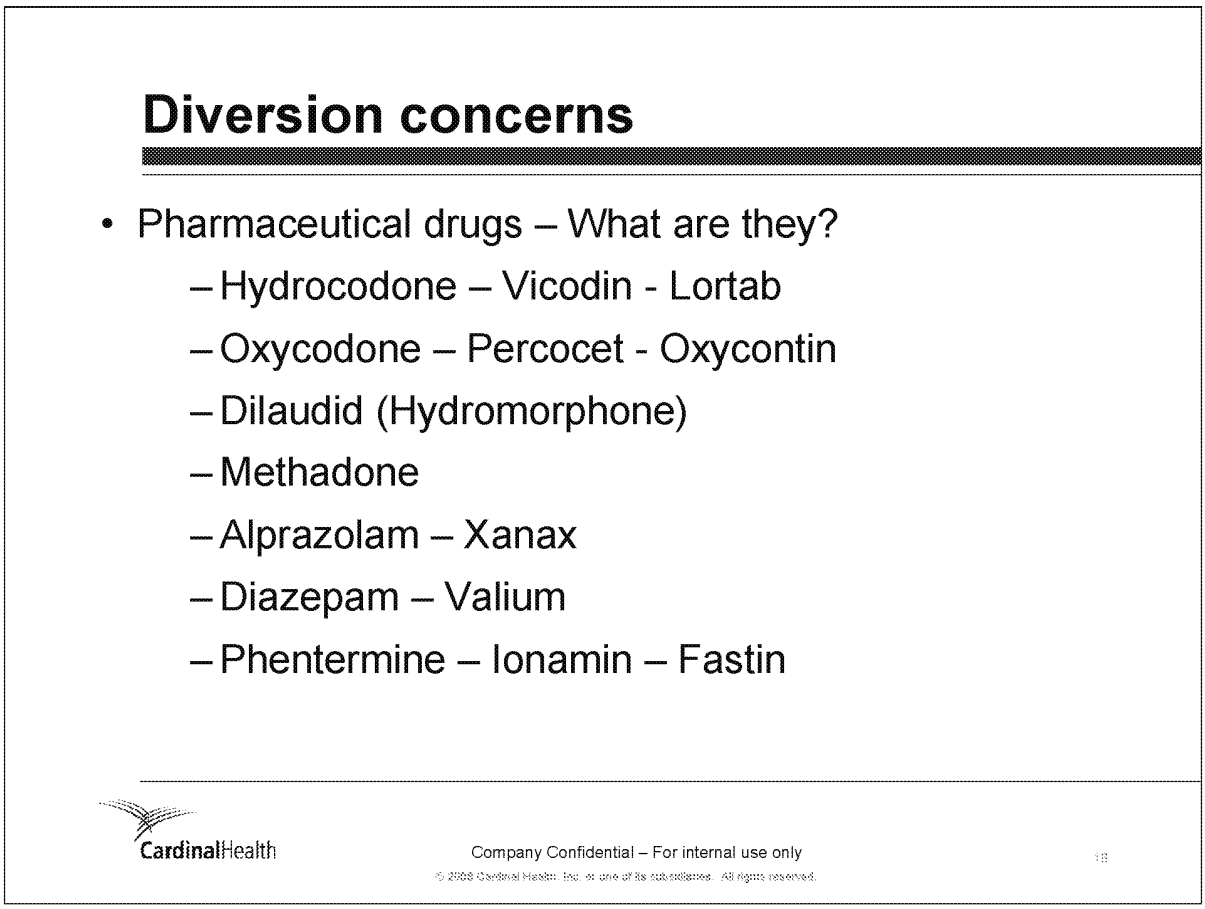


Objective: Stimulate quick discussion on methods of diversion

Timing: 5 min

Notes:What are some of the methods of diversion?
Talk at your tables and then let's see what we come up with.
Use flipchart and discuss

Transition: Ok. That was good discussion around the methods of diversion. Now let's look at what gets diverted.



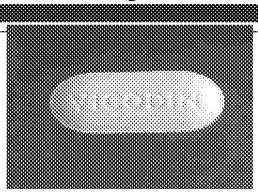
Objective: Identify most common drugs diverted

Timing: 5 min

Notes:
Ask what some of the commonly diverted drugs might be.
Write them on a flip chart – Whiteboard

Transition: We have put a face to the statistics now let's see what some of these most abused items look like and do.

Some Drugs of Concern
Vicodin™ and other hydrocodone products



Vicodin™ and other hydrocodone products: Hydrocodone is a semi-synthetic opioid similar in effects to morphine. Vicodin™ is hydrocodone mixed with acetaminophen. Hydrocodone products, when abused, can lead to dependence, tolerance, and addiction. Vicodin™ is one of the most frequently prescribed medications for pain. Other products include Vicoprophen™, Tussionex™, and Lortab Pure hydrocodone is in schedule II. Hydrocodone combination products are in schedules III and V.

http://www.justthinktwice.com/drugfacts/painkillers.cfm

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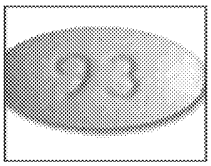
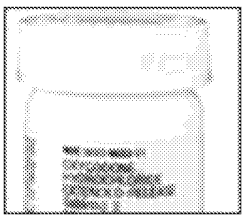
Objective: Describe the substance

Timing: 1 min

Notes: Vicodin – and more commonly the generic hydrocodone make up a huge portion of the diverted items today. This is for moderate to sever pain and usually has some tylenol, aspirin, or ibuprpfen with it.

Oxycodone





- **OxyContin™ and other oxycodone products:** Oxycodone is used as an analgesic and is formulated into numerous pharmaceuticals including OxyContin™ (a controlled-release product) and with aspirin (Percodan™) or with acetaminophen (Percocet™).
- These drugs are prescribed for pain relief. They all require a doctor's prescription and are prescribed for moderate to severe pain.
- Oxycodone is in Schedule II

http://www.justthinktwice.com/drugfacts/painkillers.cfm

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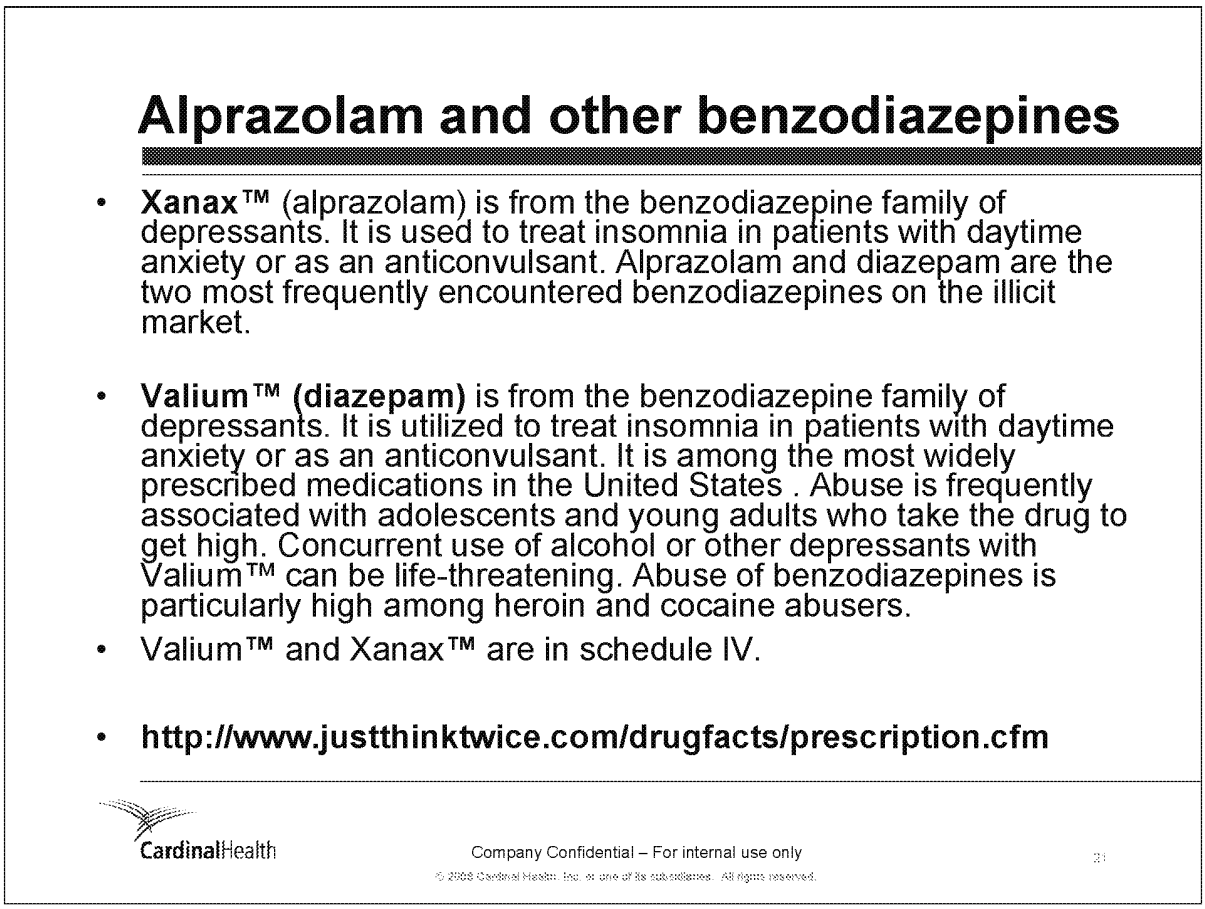
Objective: Describe the substance

Timing: 1 min

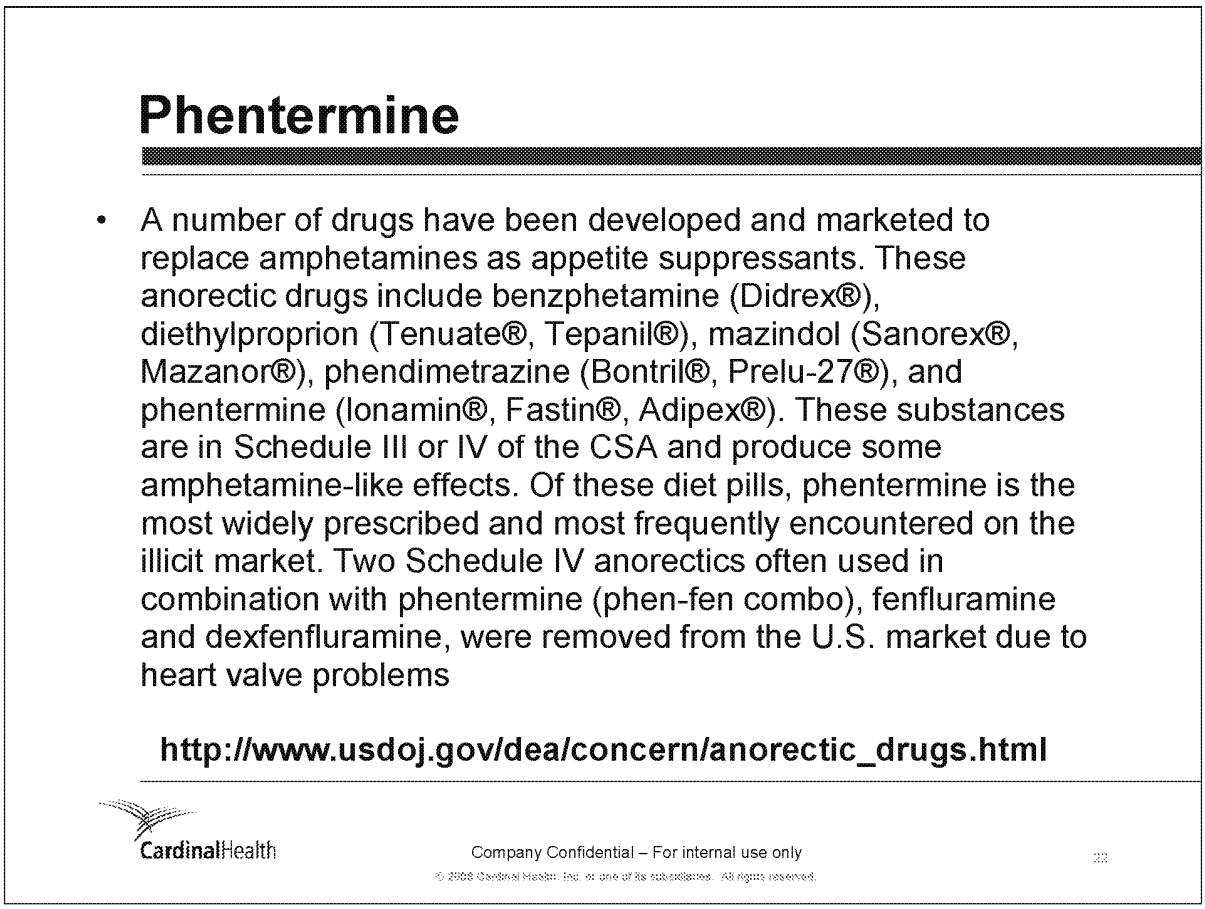
Notes: Oxycdone – in Percocet and Oxycontin. Another substance that has high abuse potential and diversion potential. Short term use and prescribed for moderate to severe pain.



Objective: Describe the substance

Timing: 2 min

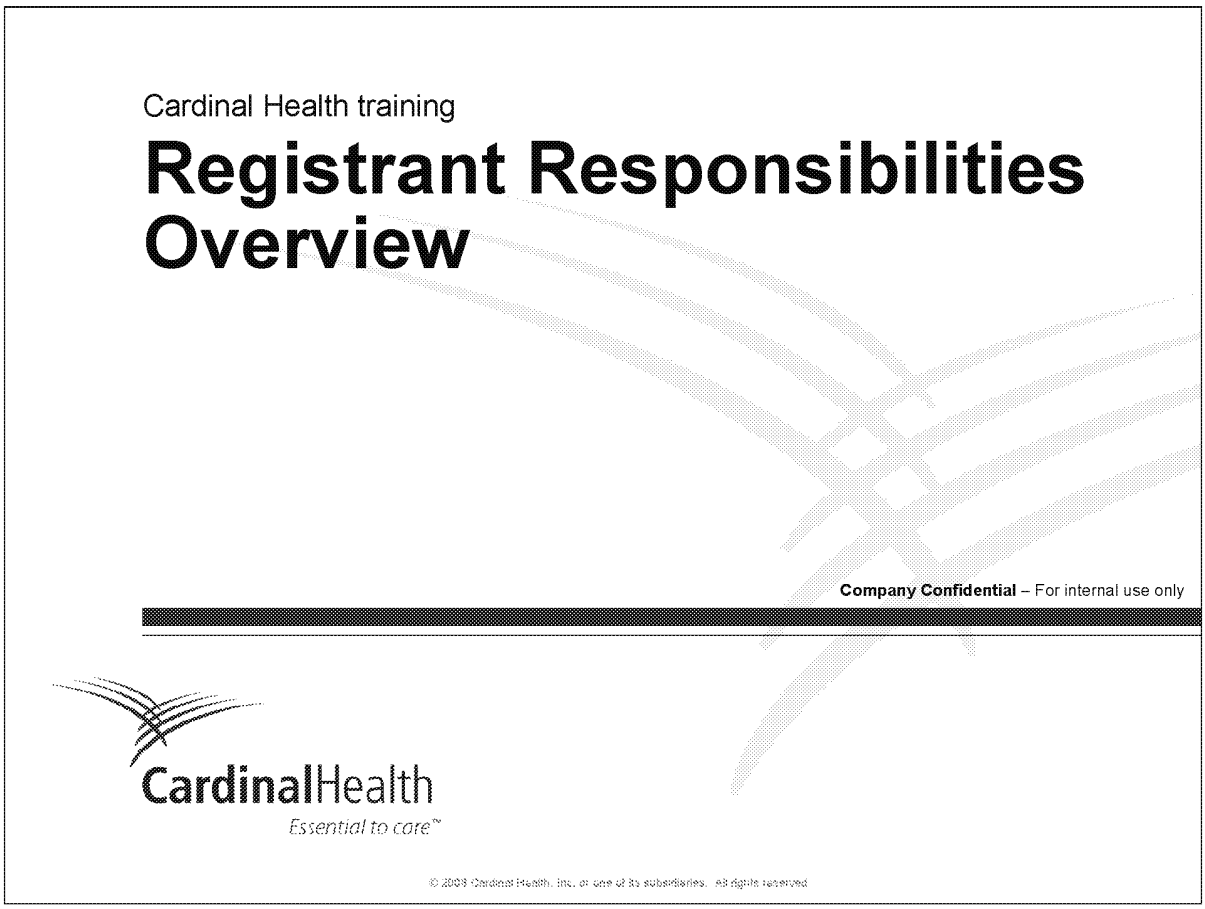
Notes: Xanax and Valium are benzodiazepines or tranquilizers. Xanax is highly addictive. It has been shown to be more addictive in this class than other substances.
It is also the most dangerous to withdraw from. Self withdrawal is extremely difficult. As you can see many of these substances are used in combination and that is a troubling thing in itself.



Objective: Describe the substance

Timing: 2 min

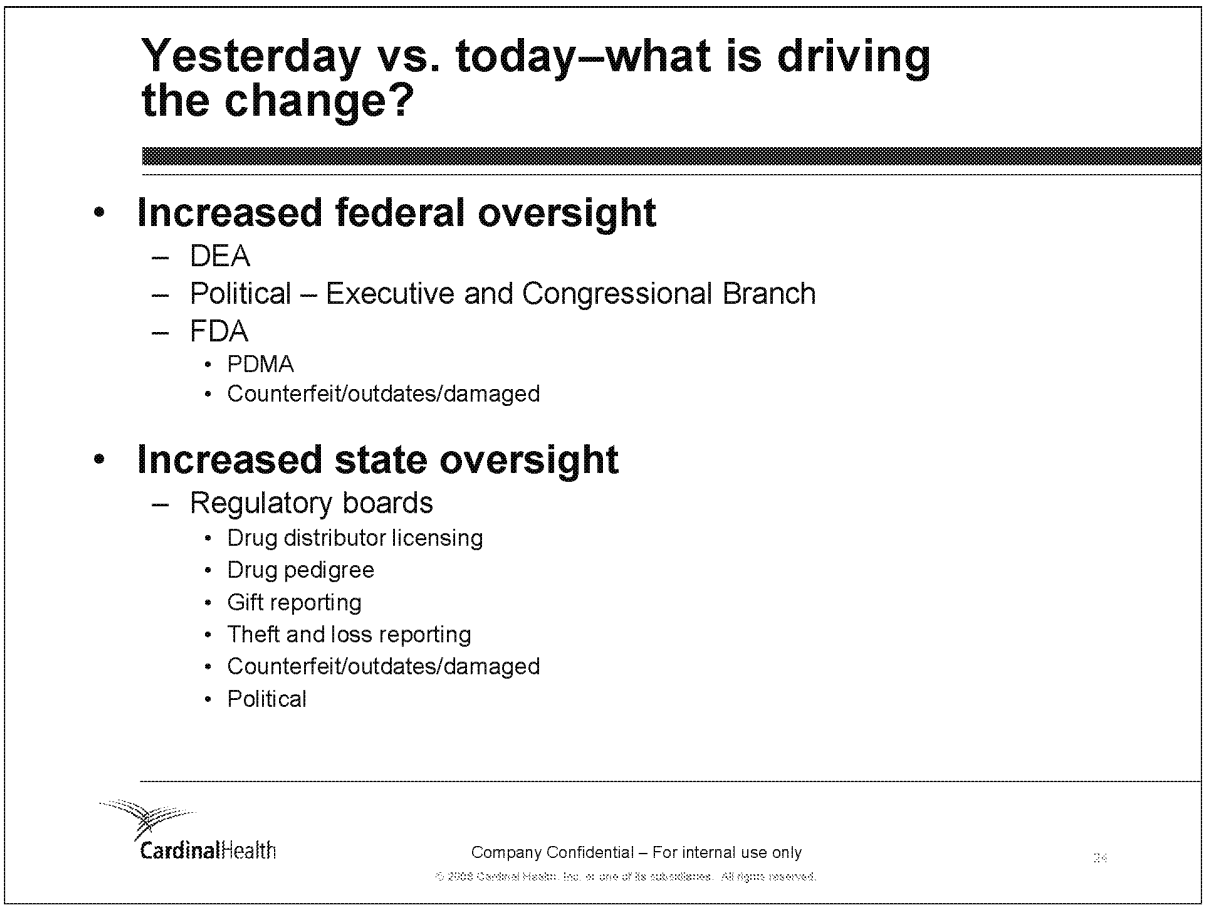
Notes: Phentermine is a later generation appetite suppressant. These have replaced amphetamine's for diet therapy. Note that this was one of the combo ingredients in PhenPhen that was withdrawn from the market because it caused heart valve problems.



Objective: Transition

Timing: 1 min

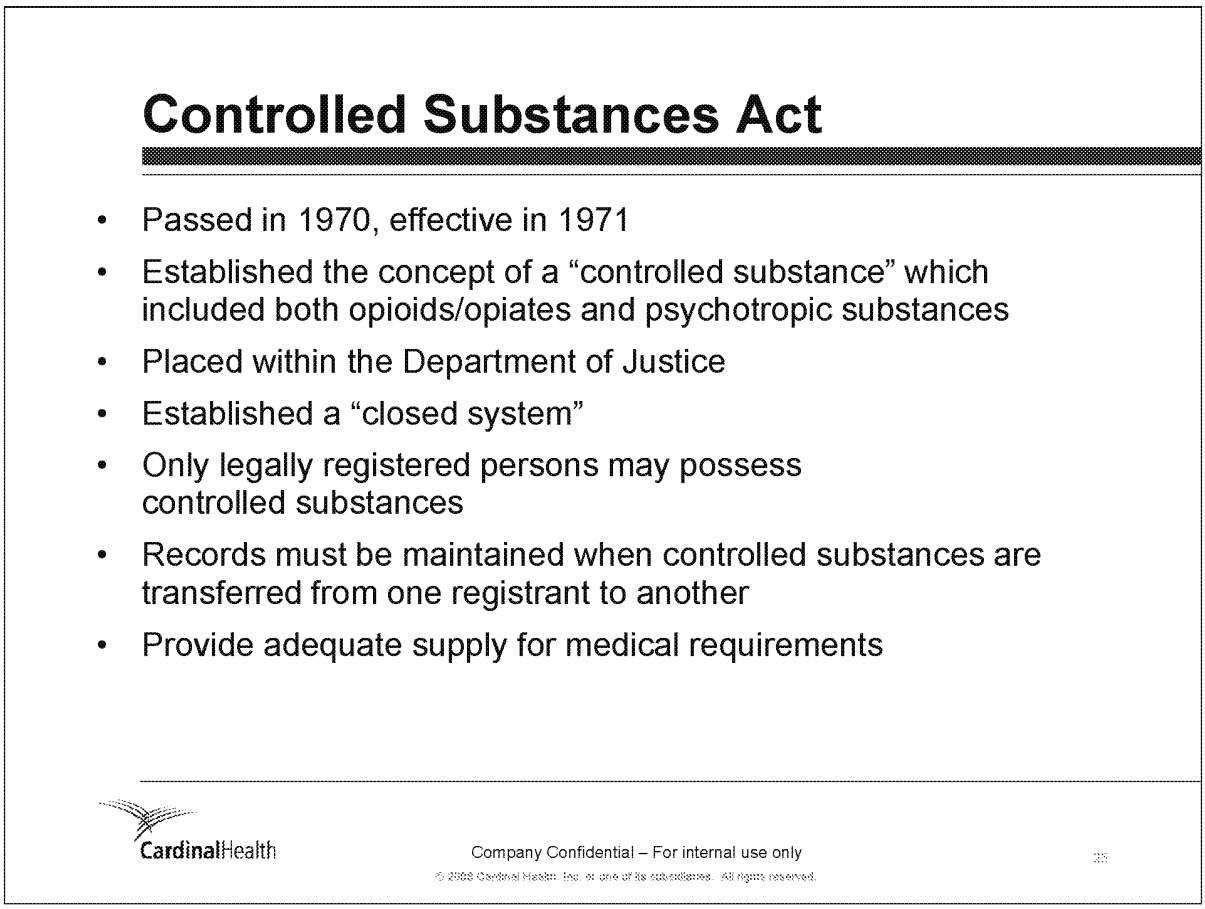
Notes We are now going to talk about some history of the DEA and what the registrants responsibilities are in regard to the regulations.



Objective: Compare/contrast the past vs present

Timing: 5 min

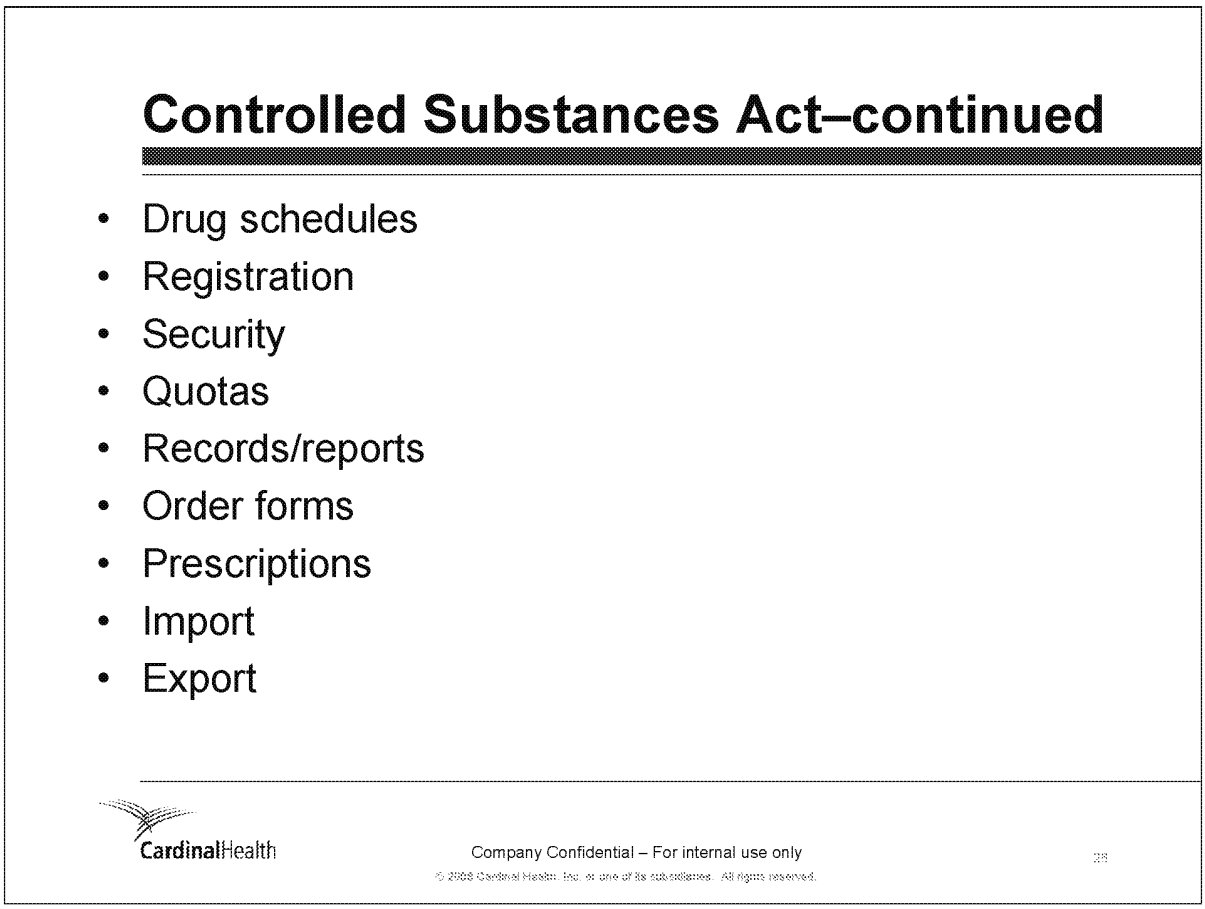
Notes: The government is engaging in greater oversite to the pharmaceutical delivery system.
The DEA is shifting more attention on the increasing abuse of prescription medicine
Some of that attention is fueled by political pressure. Congress and the Executive are becoming educated in the issue and focusing on it.
The FDA is more and more sensitive to the safety of the pipeline. The proliferation of counterfeit medicines and the introduction of unregulated medicines coming from abroad has made the FDA focus on securing the domestic flow of medication. The industry has partnered with the agency to make sure that the channel is secure by reducing secondary distributors and tightening controls on returns from customers through PDMA (Pharmaceutical & Drug Marketing Act).
The states have also seen the issues in the market place and put in their own set of fixes and regulations. Can you say pedigree?
Transition: We can see the arc of change in the recent past. Let's take a quick look at the beginnings of the DEA.



Objective: Overview of the Controlled Substances Act that created the DEA and Schedules of drugs

Timing: 6 min

Notes: Enacted during the Nixon administration
Concept of controlled substance – substances that no medical application and others that did but along with that therapeutic application had high abuse potential.
The move to the Justice Department gave the agency the prosecutory powers needed to combat the growing societal problem of drug abuse as well as regulate and monitor the manufacture.
The closed system meant that items designated as controlled substances needed a paper trail so it could be accounted for.
In order for that system to be truly closed it was required that anyone that dealt in these controlled substances had to be appropriately registered.
The act called for the monitoring of manufacture of these controlled substances so there would be adequate supply for medical requirements while discouraging over production that could lead to diversion.
Transition: This is the controlled substances act now let's talk about what those schedules are.

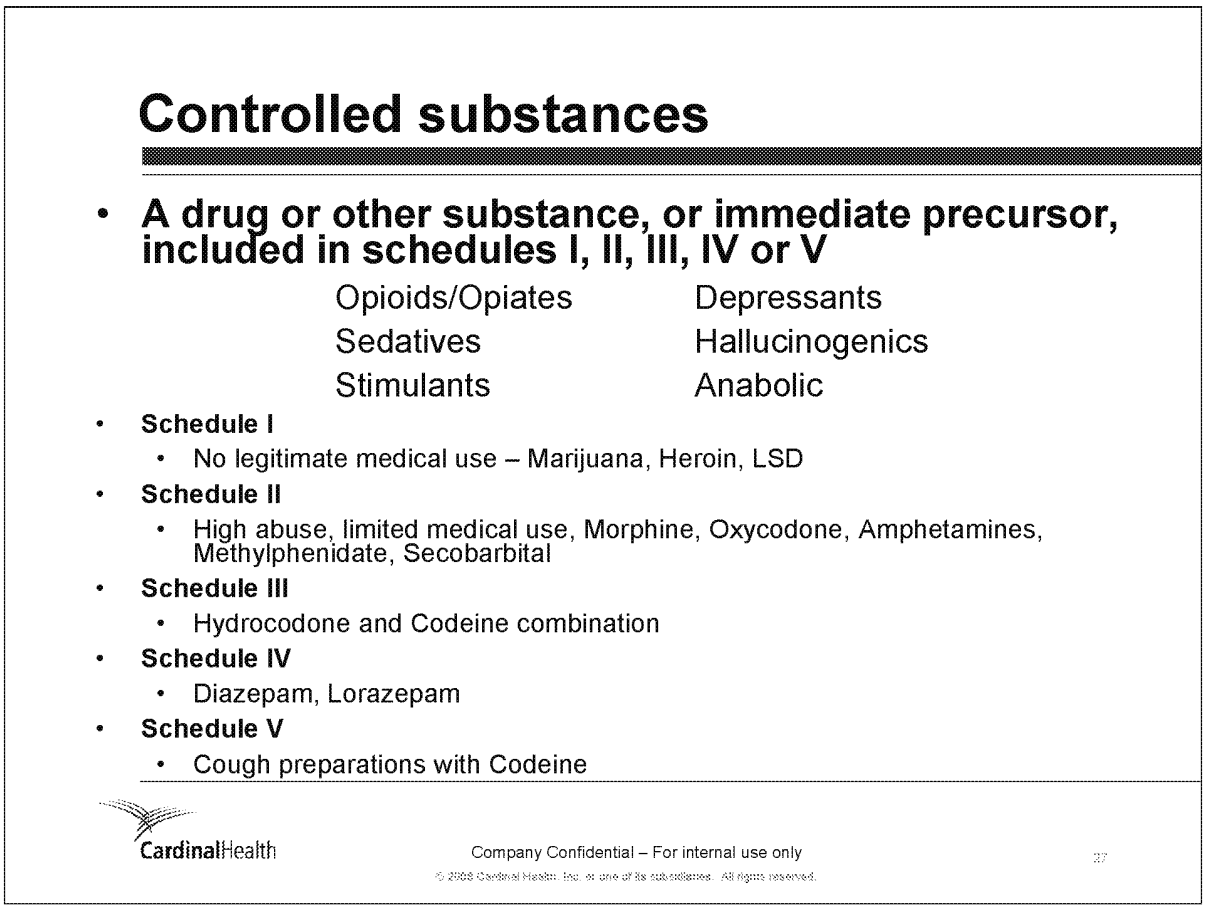


Objective: Recap the areas covered by Controlled Substances Act

Timing:2 min

Notes: Established the drug schedules
Requires registration for those handling controlled substances
Set guidelines for security around the handling of those substances
Project and control the amount of product in the marketplace
Set guidelines and requirements around record keeping and reporting back to the agency. Receiving records – purchase records – items lost/destroyed.
Established the use of the DEA form 222 as the document of record for the transfer of CII controlled substances.
Monitor the prescribing of controlled substances
Monitor/control the import/export of controlled substances.

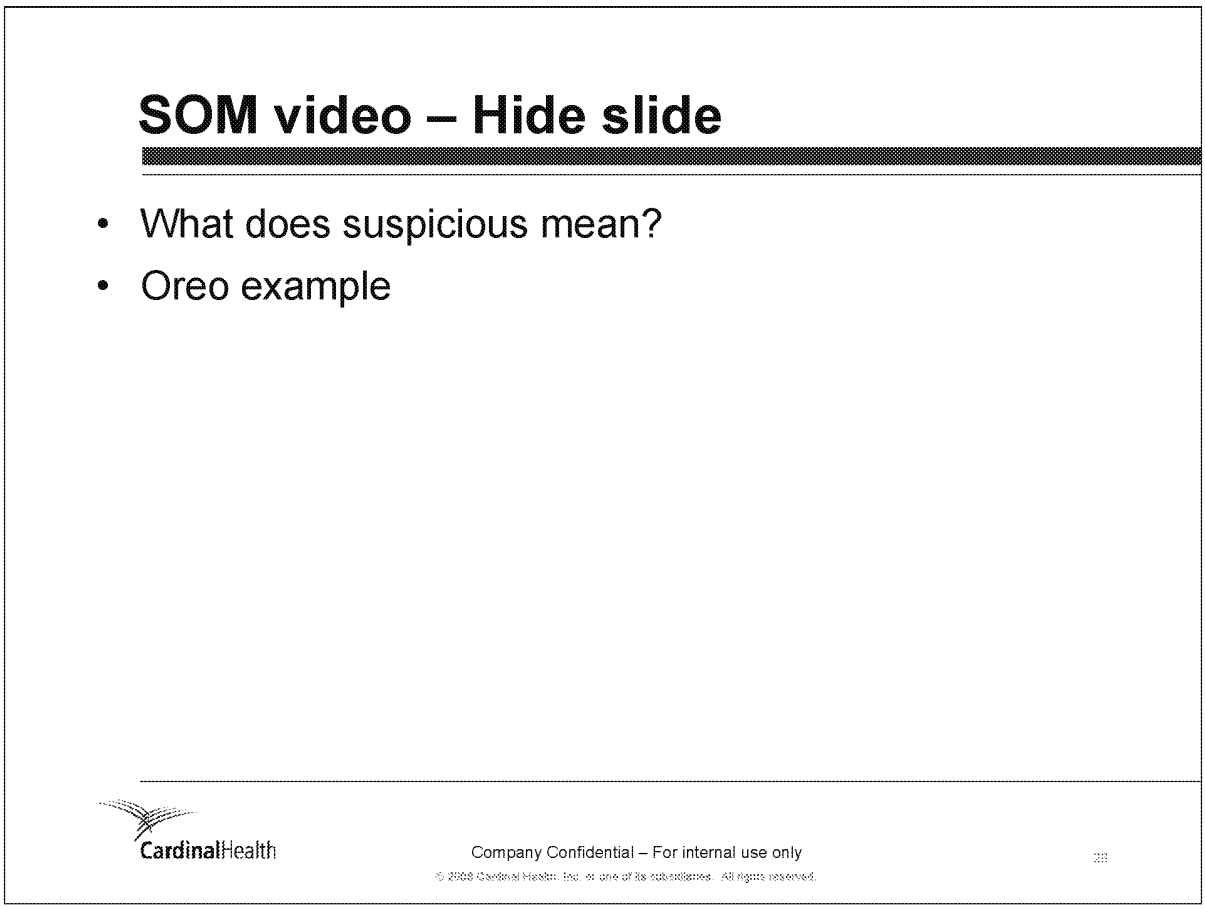
Transition: There are obviously many areas the DEA is involved with when it comes to controlled substances. You see where we can be a partner in keeping the supply chain protected. Let's start to talk about Suspicious Order Monitoring.



Objective: Discuss the establishment of schedules to classify controlled substances.

Timing: 3 min

Notes: Schedules are set based on potential for abuse and legitimate medical use.
Schedule 1 – no medical use
Schedule 2 – High abuse potential
Ect.

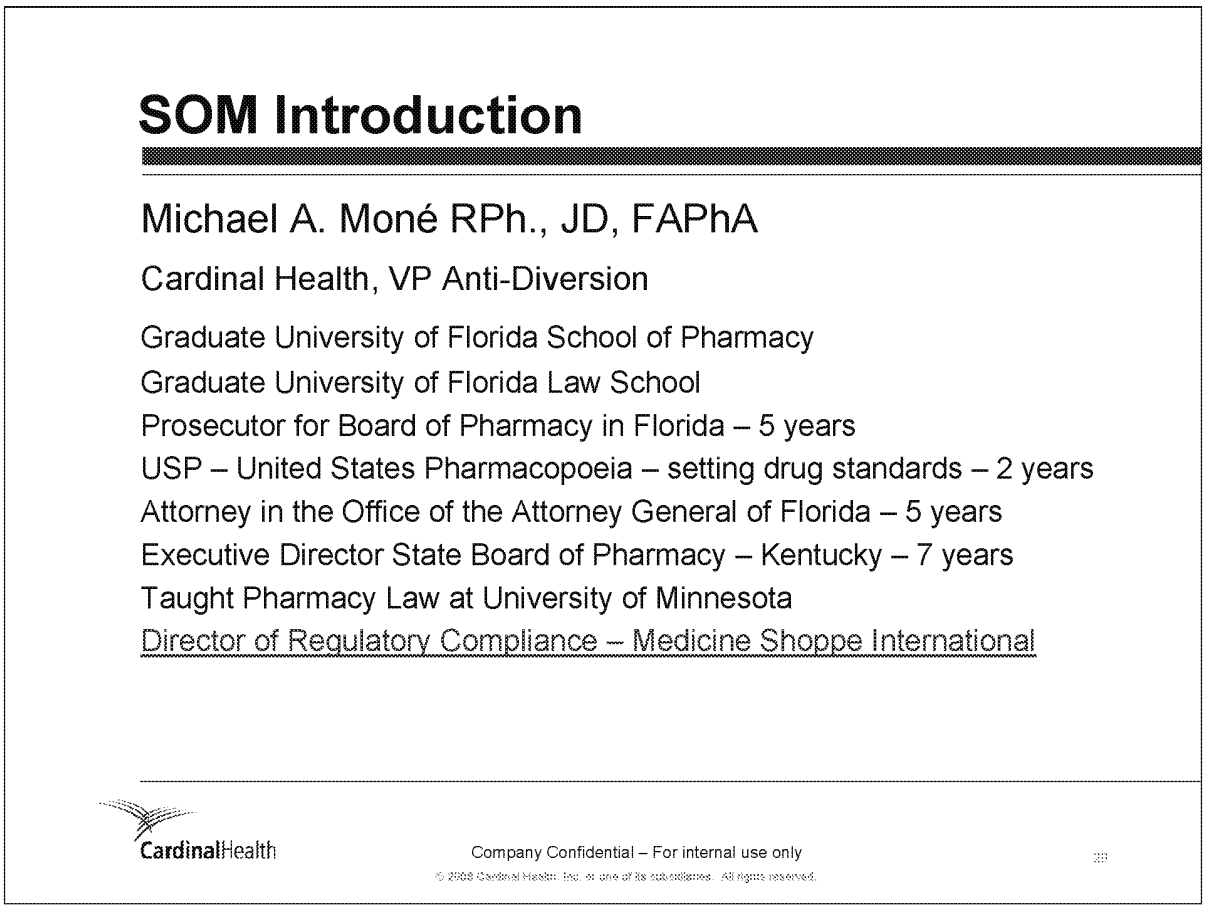


Objective: Illustrate the subjective nature of suspicious

Timing: 5 min

Notes: Before we talk about suspicious order monitoring we have try to break that down a little. Let's try to define suspicous.
Here is a scenario: In your house the rule is that nobody gets to eat the Oreo cookies until after dinner. You come home from some errands and the cookie jar that holds the Oreos has been moved a little. Is that suspicious? Everyone that thinks is please stand up.
You walk over to the jar and notice there are a few cookie crumbs on the counter. Is that from yesterday or are they fresh? Is that suspicious? You go out into the yard and there are cookie crumbs around the kid's mouth. Is THAT suspicious? Then you turn around and your spouse is walking across the yard with a bag of Oreo cookies.
As you could see around you there were different thresholds of suspicion. Suspicion is all about the gathering of data. Need to note key facts to determine when something is suspicious
In our program we have to look at the facts to determine suspicion. Give us the data. Tell me what you know.
The challenge is to capture two things. Capture the order. What does it look like? And capture the intent. What did they mean to order?

Transition: That illustrates Suspicious ordering a little. Let's let the real expert talk to us about that.



Objective: Introduce Michael Mone portion of the training

Timing: 3 min

Notes: This slide gives you the background of the next speaker. As you can see his experience in this space makes him really qualifies him to be building our Suspicious Order Monitoring program.
He is a pharmacist and a lawyer.
He has experience both in prosecuting cases for the board of pharmacy and as executive director of the board of pharmacy. He knows the customers, their patients, and the industry.

Transition: Now we will begin the video presentation of the training that Michael did in early February. I think you will find the information important and enjoy him as a speaker.

Start the video

Suspicious Order Monitoring

Michael A. Mone, R.Ph, JD, FAPhA
Cardinal Health, VP Anti-Diversion

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Objectives

- Understand the obligations of Cardinal Health for supply chain integrity
- Understand the components of the Cardinal Health Suspicious Order Monitoring Program
- Explain the Cardinal Health Suspicious Order Monitoring Program to internal and external customers
- Raise awareness of Cardinal Health employees of their role in Anti-Diversion of controlled substances

Anti-Diversion… is *everyone's* responsibility.

Prescription drug diversion is a societal problem to be addressed by a societal solution involving all participants in the prescription drug supply chain: from manufacturer to patient with the collaboration and cooperation of regulatory bodies on the state and federal levels.

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Suspicious Order Monitoring

- SOM = Suspicious Order Monitoring
  - Suspicious
  - Order
  - Monitoring
- Why do something?
  - Program developed to meet Cardinal Health's regulatory obligations to **identify, block** and **report** the intent to order controlled substances that may pose a risk for potential diversion.
  - Enhancement of our efforts in the past

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Suspicious Order Monitoring

- Why now?
  - Drug diversion of controlled substances increasing
  - Teenage access to controlled substances – death and serious injury
  - January 24, 2008 newsday.com headline
    - Mt. Sinai pharmacist charged in Vicodin scheme
  - January 26, 2008 Charleston Daily Mail
    - Actor's death renews discussion on prescription drug abuse
  - February 1, 2008 WBAY Channel 2 Green Bay
    - Two arrested in investigation of Oshkosh woman's death
      - Xanax

Thoughts on SOM

- The system must create a strategic move in the marketplace for Cardinal Health and our customers that will enable us to provide our customers with a measure of quality performance in their operations.

Thoughts on SOM

- The system is designed to be used in conjunction with other Cardinal Health products and services to have ***value*** to our customers and not be viewed as a regulatory impediment to their business performance.

Thoughts on SOM

- SOM with Cardinal Inventory Manager (CIM) and other products and services offers our customers and Cardinal Health a reasonable assurance of a legally and regulatory valid business performance.

Suspicious Order Monitoring

- Components
  - Our people
    - Know your customer
    - New Pharmacy Customer Questionnaire
  - IT Component
  - Thresholds - customized
  - Account evaluation
  - Communication
    - Across all Cardinal Health business units
    - All roles involved in SOM

Know Your Customer Program
New Pharmacy Questionnaire

- Required as part of account approval process for all new retail independent and wholesaler accounts.
- Pharmacy Business Consultant is responsible for filling out the questionnaire and submitting it to Corporate QRA for approval.
- Information should be obtained from the pharmacy owner and signed by the owner.
- The Pharmacy Business Consultant is the first contact for Cardinal Health in preventing diversion.
- The questionnaire must be taken seriously and must be filled out thoroughly and accurately.

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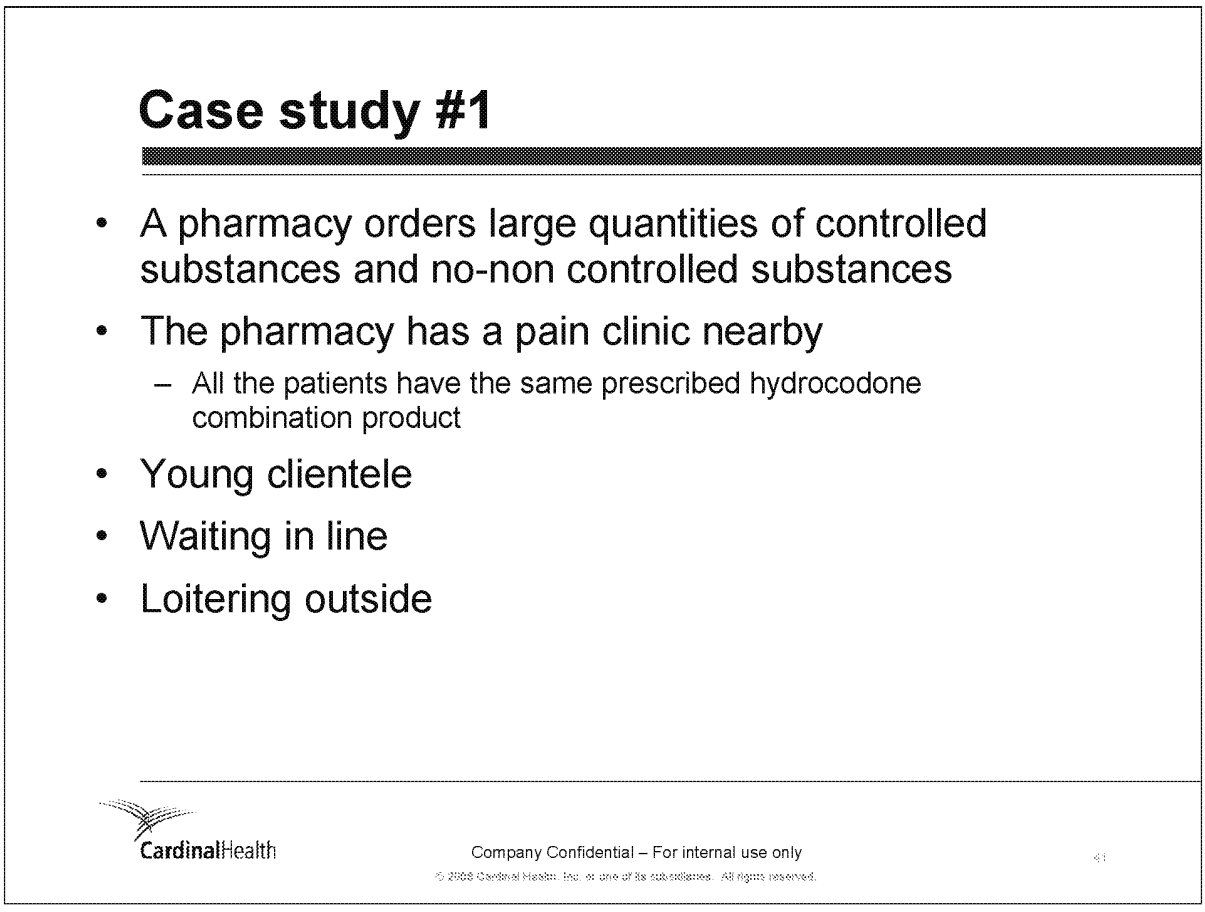
What are "Red Flags"

- Looking for signs of Internet activity (shipping supplies, lack of walk-in customers, etc.) and filling prescriptions from questionable "pain clinics". Red flags would include
  - Pharmacies with minimal or no front end merchandise.
  - Pharmacies with little or no walk-in business.
  - Pharmacies with primarily cash customers.
  - Pharmacies ordering a high percentage of controlled substances relative to non-controlled substances.
  - Pharmacies ordering excessive quantities of a limited variety of controlled substances.
  - Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled?
  - Does the pharmacy solicit buyers of controlled substances via the Internet?

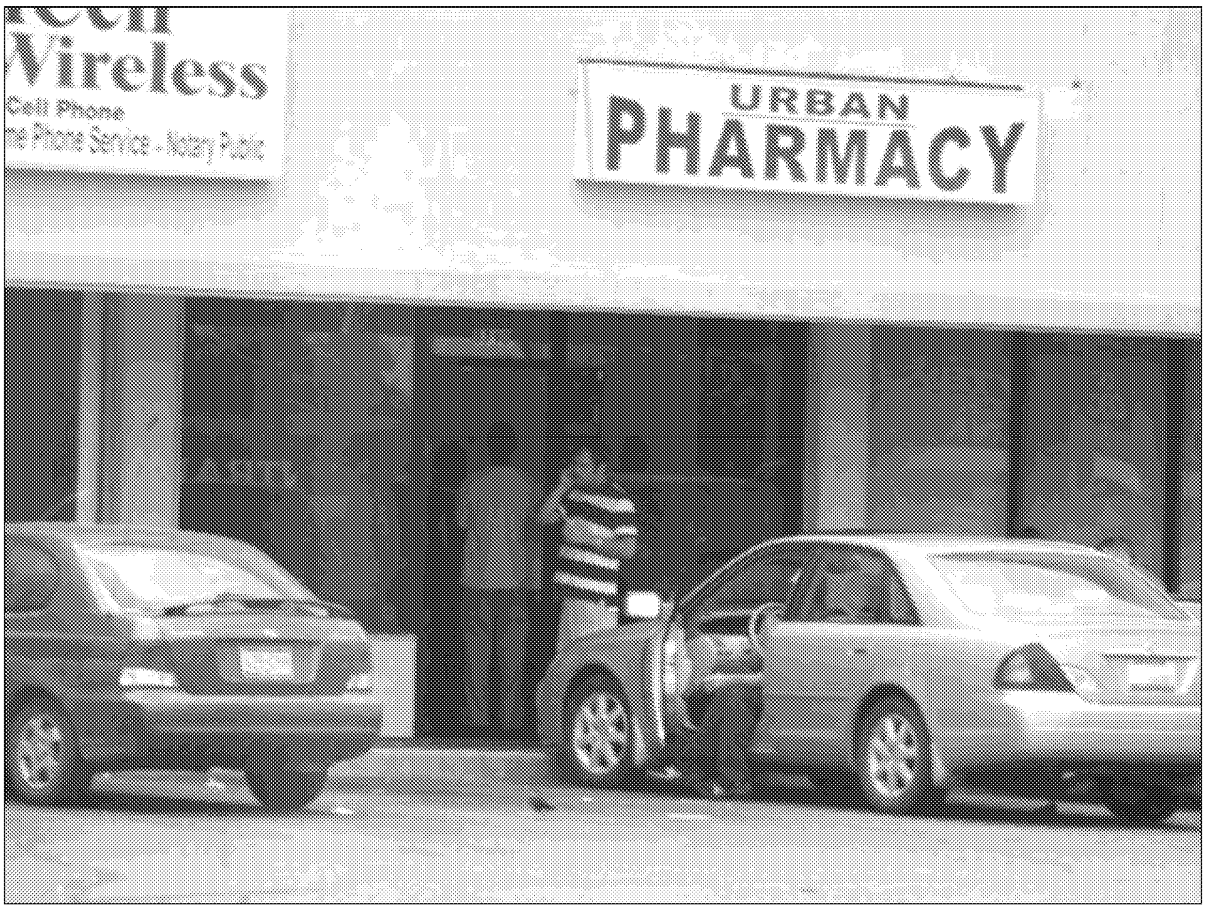


Objective: Case study

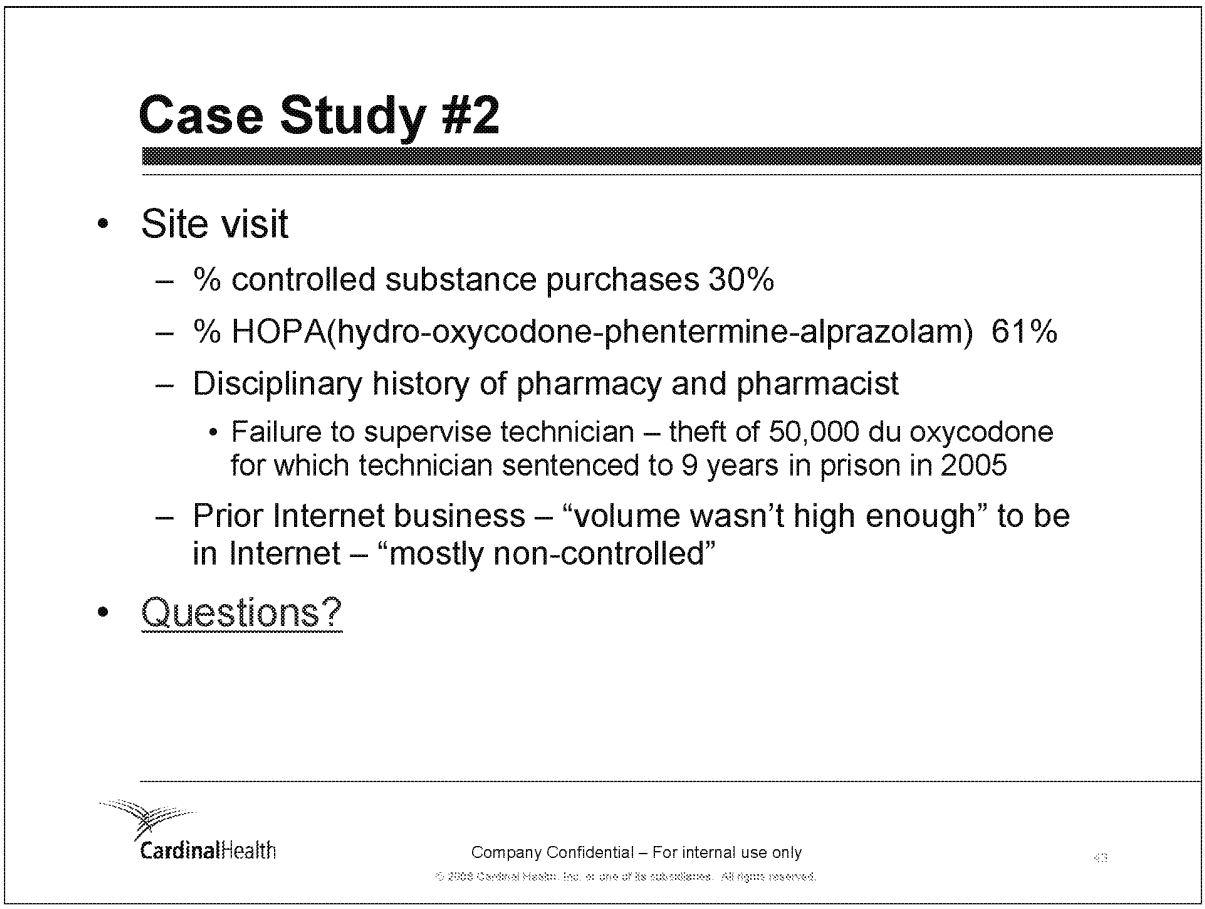
Timing: 3 min

Notes:
Here is a scenario regarding a potentially suspicious pharmacy.
Emphasize the pain clinic nearby.

Is this a suspicious pharmacy? Why?
Could it serve a legitimate purpose in the community?
Show the photo.
THIS is that pharmacy. How does it look to you?
How many red flags do you see raised here?



Does this look like your community pharmacy?
Notice the line inside and people hanging around. From what you can see it is not a 'mix' of clientel.
No family with kids or senior citizen picking up their medication.



Objective: Case study

Timing: 3 min

Notes: Big concern with disciplinary action
The comment that volume wasn't high enough and the 'mostly non-controlled' mean that they weren't getting paid enough and they DID ship SOME controls.
Is this one of the good ones?

Contents of the New Pharmacy Questionnaire

- General Information about Pharmacy, its owner and its pharmacist in charge
  - Goal is to make sure that the pharmacy is registered with the DEA, those behind the pharmacy are licensed and can easily be contacted – provides for accountability.
  - Make sure that a clear picture is formed regarding all other pharmacies owned by the same owner.
  - Questionnaire asks for compliance history – has the license ever been revoked? This could be a red flag and might indicate a lack of commitment to compliance by the pharmacy's owner or operator.

New Pharmacy Questionnaire (con't)

- Other suppliers
  - It is important to understand whether the customer has other suppliers so that you can make a determination, where possible, of the total amount of controlled substances the customer will be obtaining.
  - While it might be difficult to ascertain information about other suppliers, you should at least document your efforts to try to obtain that information. If your customer will not tell you, you should note that on the form.
  - You should reassure your customer that you are not seeking that information for competitive advantage, but to try to comply with enhanced anti-diversion standards being set by DEA.

New Pharmacy Questionnaire (con't)

- The Pharmacy's Customers
  - Certain types of customers might raise concerns for the regulators or might, on the other hand, justify a seemingly excessive order. Context is important.
  - For example, if your customer services a nursing home, an oncology center, or a hospital, that customer would probably have larger orders than a customer serving individuals who walk in – there are simply more patients to service.
  - Similarly, if a pharmacy fills prescriptions exclusively for individual walk in customers with little to no phoned in prescriptions, that might be suspect as well.

New Pharmacy Questionnaire (con't)

- Out of State Shipments or Out of State Customers

  Why is this important?

  – In general, it should not be necessary for a patient of an independent pharmacy to go outside his state of residence to fill a prescription. (Border cities are an exception.)

  – The further away a pharmacy is from the patients for which it fills prescriptions, the more suspect it is. The PBC should inquire further as to why the pharmacy's customers are located in different states.

  – Large amounts of shipments out of state, coupled with little walk-in traffic, is another red flag.

New Pharmacy Questionnaire (con't)

- Pharmacy's Affiliation with Internet website
  - A critical red flag. DEA has found in recent years that many pharmacies supply controlled substances over the Internet through on-line orders that might not have been the result of a valid doctor-patient relationship.
  - If you are dealing with a pharmacy that fills on-line orders, you must scrutinize more carefully.
  - A factor that you must consider is, what percentage of total Rx sales are generated from a website. The greater the percentage, the more potentially risky the sale.
  - Also need to consider type of on-line ordering. Is it the customer's own website that allows new prescription requests? Or is it the pharmacy filling orders for another Internet website?

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New Pharmacy Questionnaire (con't)

- Method of Payment
  - The DEA has indicated that if a large percentage of a pharmacy's total sales are for cash sales, this is a potential red flag.
  - Be careful to understand the percentage breakdown of cash vs insurance payments or Medicare/Medicaid reimbursements. Be sure to ask the pharmacist why the breakdowns are the way they are. Is the neighborhood in which the pharmacy is located an area in which most residents receive public assistance? Would you expect more Medicaid than cash payments in such a case?
  - Are sales of other products at the pharmacy paid for in the same manner as controlled substances?

New Pharmacy Questionnaire (con't)

- Pharmaceutical Needs
  - DEA has indicated that a large percentage of controlled substance orders compared to total orders might be a red flag for diversion occurring.
  - You should try to ascertain the expected product mix a customer anticipates ordering.
  - If a pharmacy intends to purchase only controlled substances or a high percentage of controlled substances, an explanation must be provided and noted on the questionnaire.

New Pharmacy Questionnaire - data

- Component of know your customer
- New account
  - New store
  - Existing store, new to Cardinal Health
- Evaluation is customer specific
  - New store – small category
  - Existing store – 12 month total dollar purchases from prior wholesaler and if computer can provide a breakdown of the monthly purchases of controlled substances

New Pharmacy Questionnaire

- Key information
  - Ownership
  - History of purchases
  - Power of Attorney
  - Location
  - Business model
    - Compounding
    - LTC
    - Hospice

Pharmacy DEA Compliance Agreement

- Required to be signed by the Pharmacy ***Owner***.
- Other distributors ask for similar certifications.
- Purpose is to have the pharmacy agree that they will not fill prescriptions that are not issued for a legitimate medical purpose and in the normal course of professional practice.
  - This protects Cardinal Health. In most instances, we are not in a position to investigate the individual prescriptions filled by our customers. Therefore, we ask them to certify that they are not filling prescriptions that do not appear to be issued for a legitimate medical purpose in the normal course of professional practice.
- The agreement also asks the customer to be alert for "red flags" that may indicate suspicious prescriptions.

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Our People

- Know your customer training
  - On-line training
  - Documentation
  - Application
  - Sea-change in relationship
- Validation of customer purchases
- Focus is accountability and knowledge
- Awareness of business practices of our customers
- Build relationships and offer tools to assist customers like CIM

The Internet

- DEA policy can be found at:
  - http://www.deadiversion.usdoj.gov/faq/internetpurch.htm
- Essentially: no valid prescriber-patient relationship = no valid "prescription" = can't dispense pursuant to the "prescription"
- Prescription must be for a legitimate medical purpose
- Historically, validity of prescriber-patient relationship was founded in state law
- Internet has not changed the analysis, just jurisdiction and enforcement
- Administrative, civil and criminal prosecutions

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Diversion

- Multiple methodologies
- Internal
- External
  - Our customers
    - All market segments or classes of trade
    - Internet
    - Secondary sales of contracted pharmaceuticals
  - Pharmacy employees, patients themselves, pharmacists
    - Money
    - Unlawful use

Excerpt from DEA Letter 12/27/2007

- Distributors are required to:
  - maintain effective controls against diversion
  - report suspicious orders of controlled substances when discovered
  - conduct an independent analysis of suspicious orders prior to completing a sale
  - determine whether controlled substances are likely to be diverted and to take action to prevent the diversion

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Excerpt from DEA Letter 12/27/2007

- Characteristics of suspicious order
  - deviation in normal pattern
  - significant change in size
  - one product or group of products
  - percentages of purchase mix without validity

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IT Component

- A tool to assist in our evaluation
- Data mining for patterns and practices
- Continuous review and where appropriate revision of parameters for each customer
  - Increase or decrease
- In future to be used to establish pro-active analysis
- Designed to map purchases to established patterns of valid dispensing

Thresholds

- Criteria
  - Class of trade
  - Size
  - Volume
  - Dispensing characteristics
- Categories
  - Small, medium, large, absolute maximum
- Non-discloseable
  - Capture intent

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Thresholds

- Establishment
  - Statistically significant
  - Grouped by active ingredient
  - Standardized customers into cohorts of similarly situated patterns & characteristics
  - Flexibility for customers to order within a range and to permit growth of the pharmacy business with validation

Thresholds

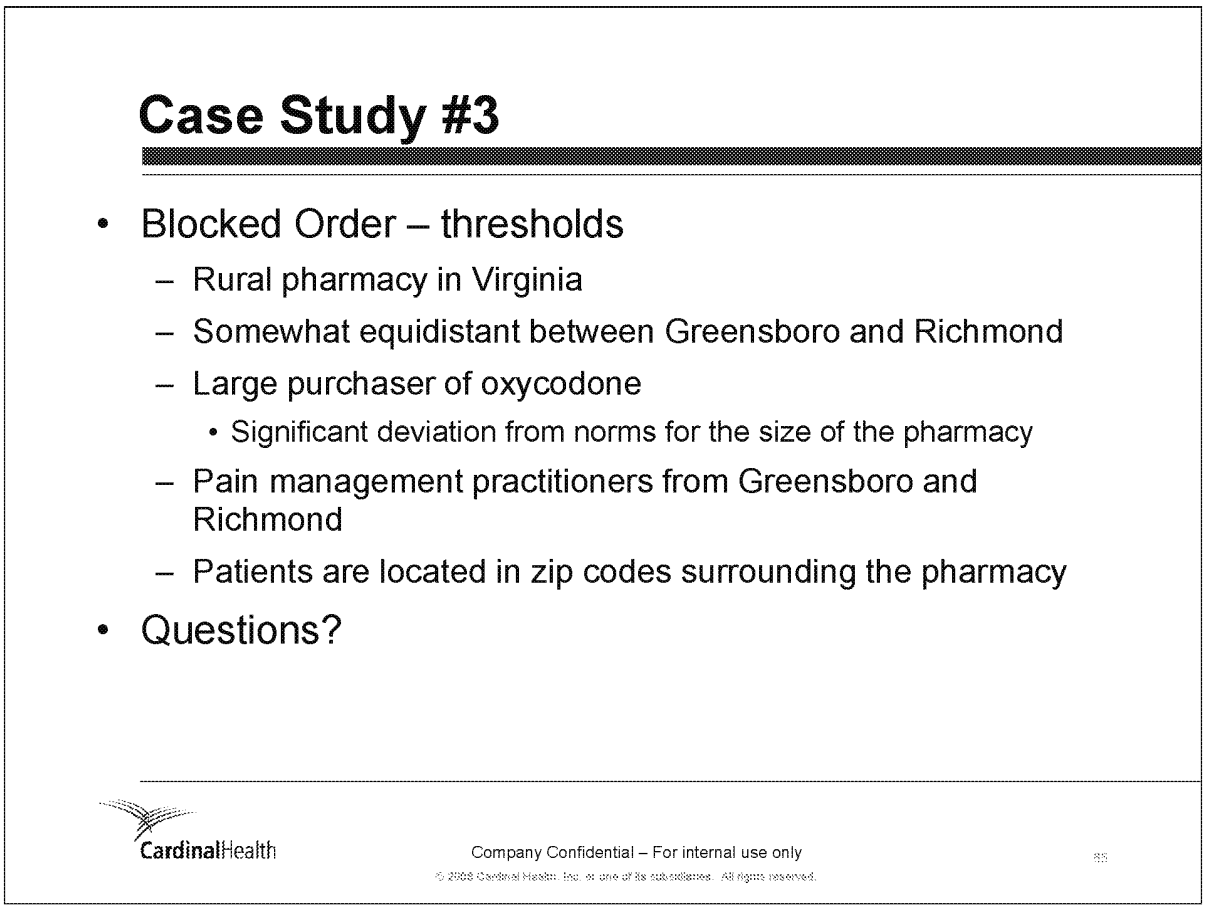
- Statistically designed to appropriately group similarly situated customers into groups
- Data will drive decisions - if our customers are normal, the number of customers that exceed their initial thresholds should be not more than 2.5% during initial start-up
- Adjustments for QRA thresholds will be both increases and decreases, i.e. customized to the customer
- Based on DEA Certificate of Registration Number

Thresholds

- "Excess" order or intent to order
  - Held orders – quantity exceeds threshold
  - Invoice informs customer
    - Held Pending Regulatory Review
  - IT component prepares a report of customer patterns and order practices for evaluation
  - QRA Evaluation
    - Turnaround
    - Customer notice
      - Awareness of program
      - Effect on them

Thresholds

- Cut (Block or Held) Order
  - Subsequent order/intent to order
  - During QRA review of held order
  - Invoice notice
    - Cut Per Regulatory Review
- Prepare our customers for the implementation of this new regulatory environment
- Process developed and implemented simultaneously in a rather aggressive timeframe
  - Program was in the development stages

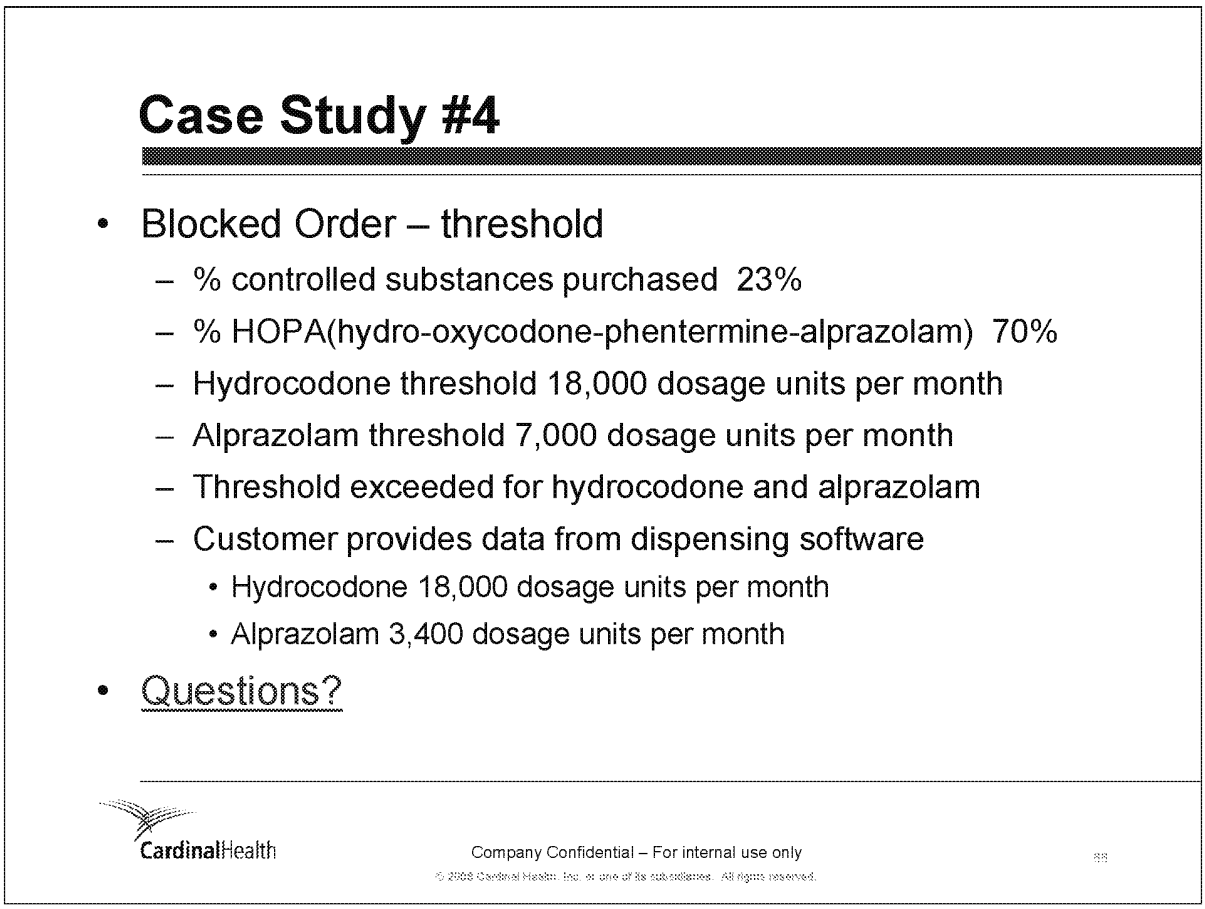


Objective: Case study

Timing: 5 min

Notes: Set the stage for the discussion. Give the tables 5 min to make a decision.

This customer was ok. It was determined that because they were rural their patient population had to travel to the cities to go to the bigger hospitals.
Setting – Rural
Location of hospitals
Patients all local
Factors in determining that it was appropriate.



Objective: Case study

Timing: 5 min

Notes: Let the table review and discuss

Do the math.
The product is going somewhere
Potential employee theft or diversion

QRA Evaluation

- Review of 12 month historical purchases
- Questionnaire sent by Sales Operations to customers to inquire about order – the why
- Questionnaire sent to QRA by customer – the plausibility evaluation
- Verification by site visit
  - Sales
  - QRA

QRA Evaluation

- Order plausible
  - increase threshold
  - held order released
  - customer may purchase additional quantities
- Order not plausible
  - keep threshold
  - no further orders permitted
  - site visit required

QRA Evaluation

- Order not plausible and suspicious
  - order blocked
  - suspicious order reported to DEA
  - sales notified
  - customer terminated from purchasing
    - Controlled substances or
    - In totality

QRA Evaluation

- Balancing of interests based upon available data
- Identify suspicious orders & report to the DEA
  - How much information is available to Cardinal Health?
  - How much responsibility does Cardinal Health have for physician and pharmacy conduct?
- Preserve legitimate business relationships
- Meet legitimate medical/patient requirements
  - We get the right drugs to the right people who administer or dispense the right drugs to the right people who need them.

QRA Evaluation

- **Risk management**
  - Can Cardinal Health support an account that might be legitimate or might not be legitimate?
  - Does Cardinal Health have to know that the physician / patient relationships are legitimate?
  - Does Cardinal Health have to know that the physician / pharmacy relationships are legitimate?
- **Can Cardinal Health know the answers to these questions?**
- **Cardinal Health must rely in part on regulatory bodies to discharge their societal obligations in a timely manner.**

Thresholds

- Phase II
- 101 categories of controlled substances and drug classes
- Some customers will exceed thresholds for several controlled substances and drug families
- Some customers may receive multiple questionnaires, however, if the data is available and validated, adjustments will be made at the initial analysis
  - Sometimes there is no basis in the data with which to justify the change without another questionnaire

Proactive Threshold Analysis

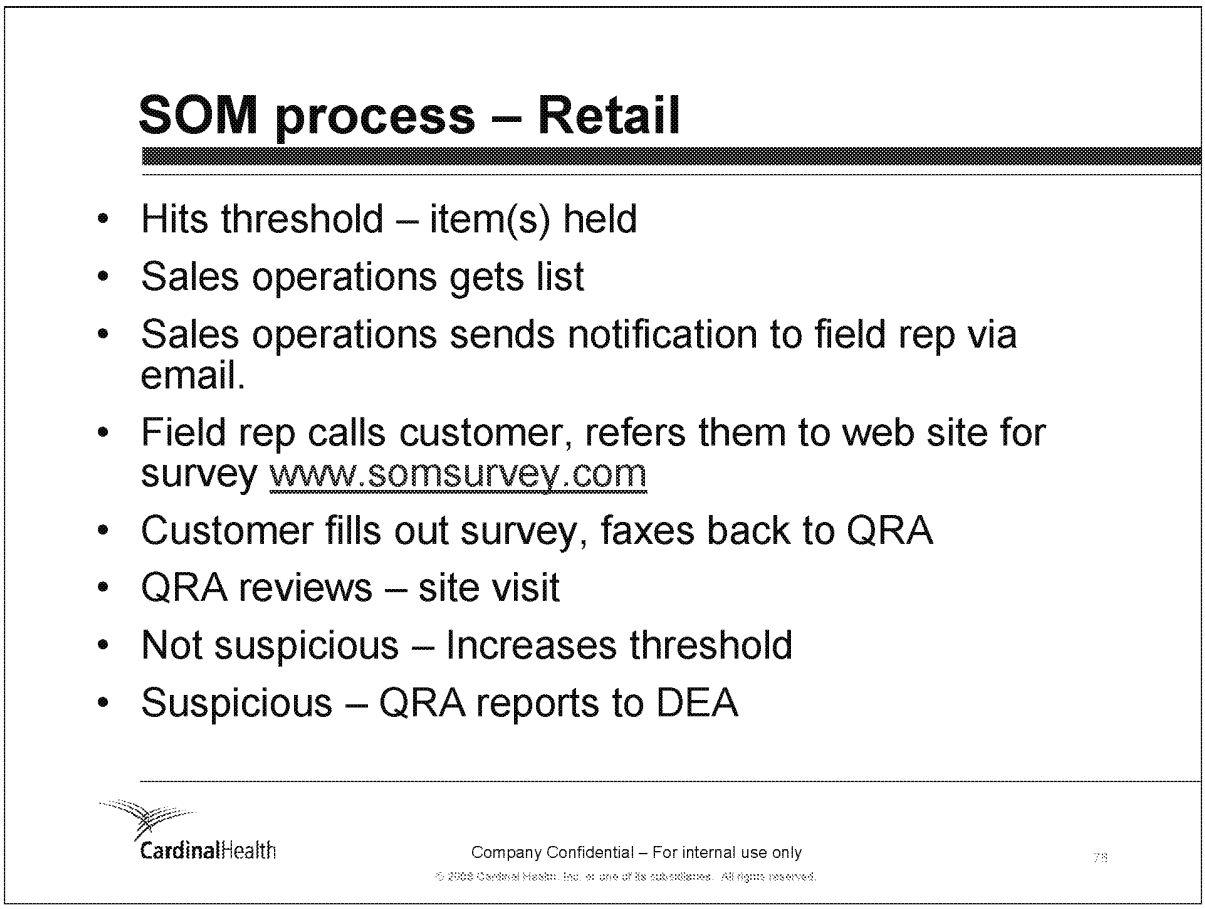
- Our people
- Know your customer
- Gather information and provide to QRA
  - Significant change in business
    - Hospice contract
    - File purchase of another pharmacy
    - Location change into Medical Center
    - Addition of new Cancer Center

Retail Independent Process

- Threshold order blocked
- IT report generated
- Threshold order analyzed
- Questionnaire sent
- Questionnaire information validated
- Decision made by QRA
  - Increase
  - No increase
  - Report as suspicious

Decision Impact

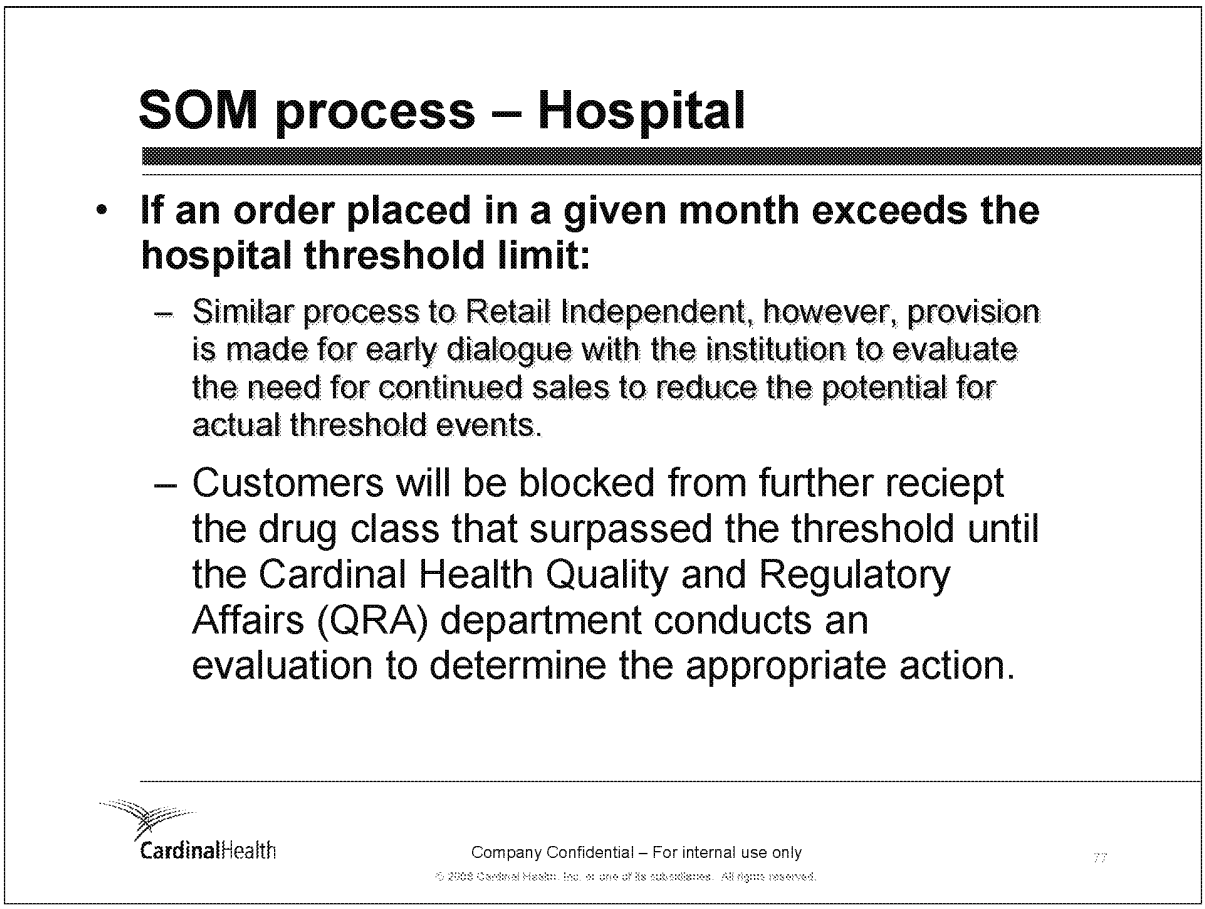
- If the order is justified, additional product from the original order may be released up to the new threshold amount
- If the threshold is not increased, the remaining product from the original order will be cut.
- If the size of the original order is not justified, QRA will send a report to the Drug Enforcement Administration (DEA) and a block will be applied to all families of controlled substances.



Objective: Describe the process (may change over time)

Timing: 5 min

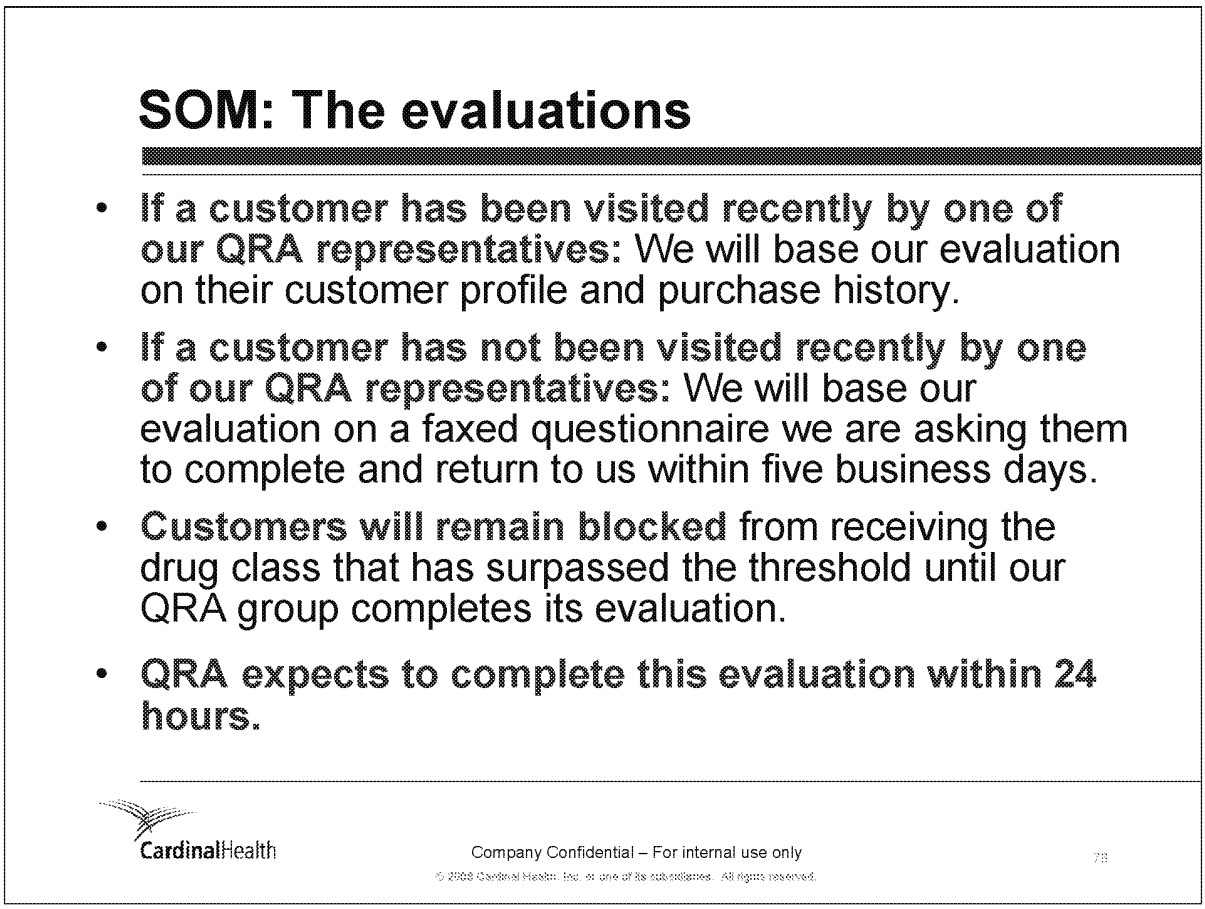
Notes: See above



Objective: Describe process

Timing: 5 min

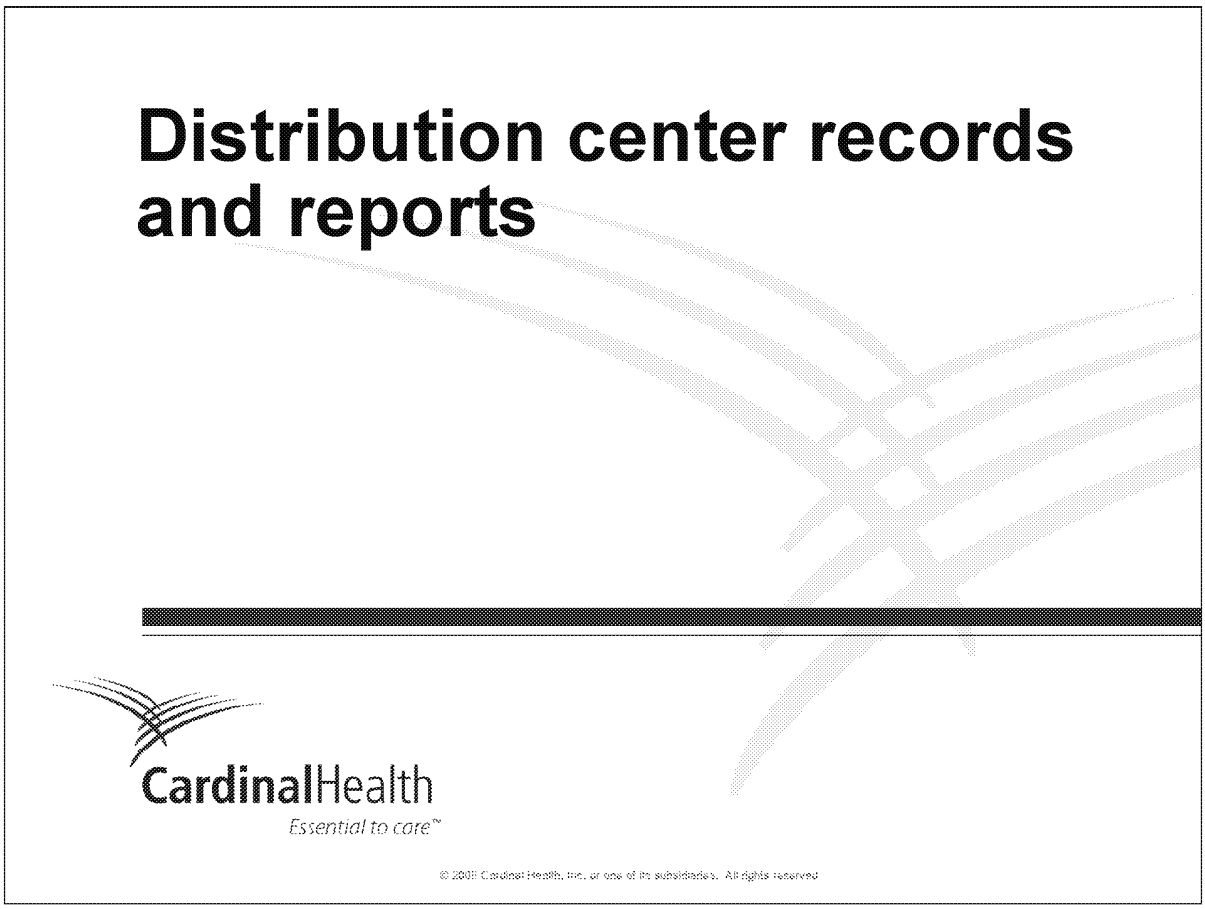
Notes: Process will parallel what is already occurring with some differences to ensure patient safety.



Objective: Describe process

Timing: 5 min

Notes: Speak to the process and confirm that it is being finalized.

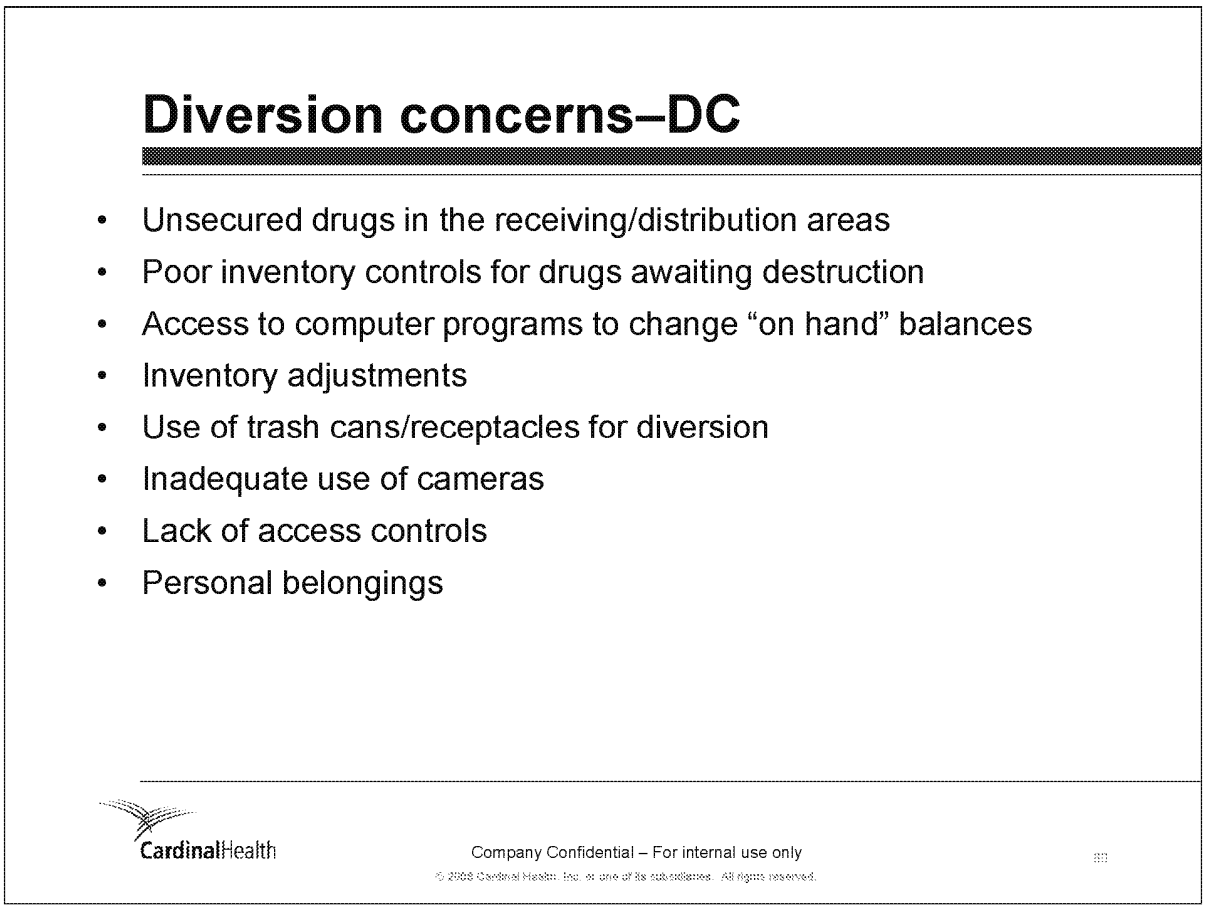


Objective: Transition from SOM back to operational discussion

Timing: 1 min

Notes: Wrap up discussion around SOM and move on.

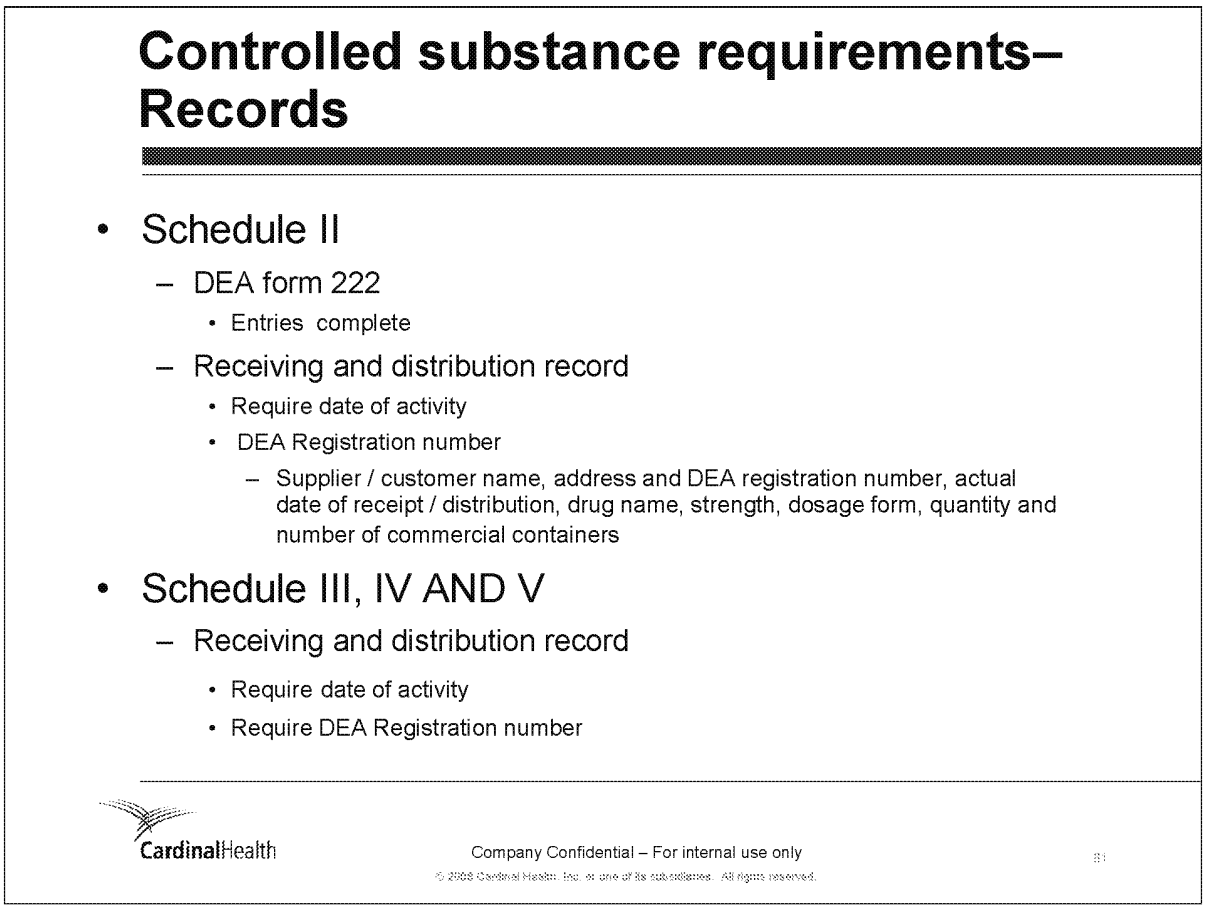
Transition: Michael did a great job of communicating our commitment and goals around suspicious order monitoring and put the issues in perspective.
Now let's talk about the things we need to do within the DC to prevent diversion.



Objective: Discuss areas of vulnerability at the DC level

Timing: 3 min

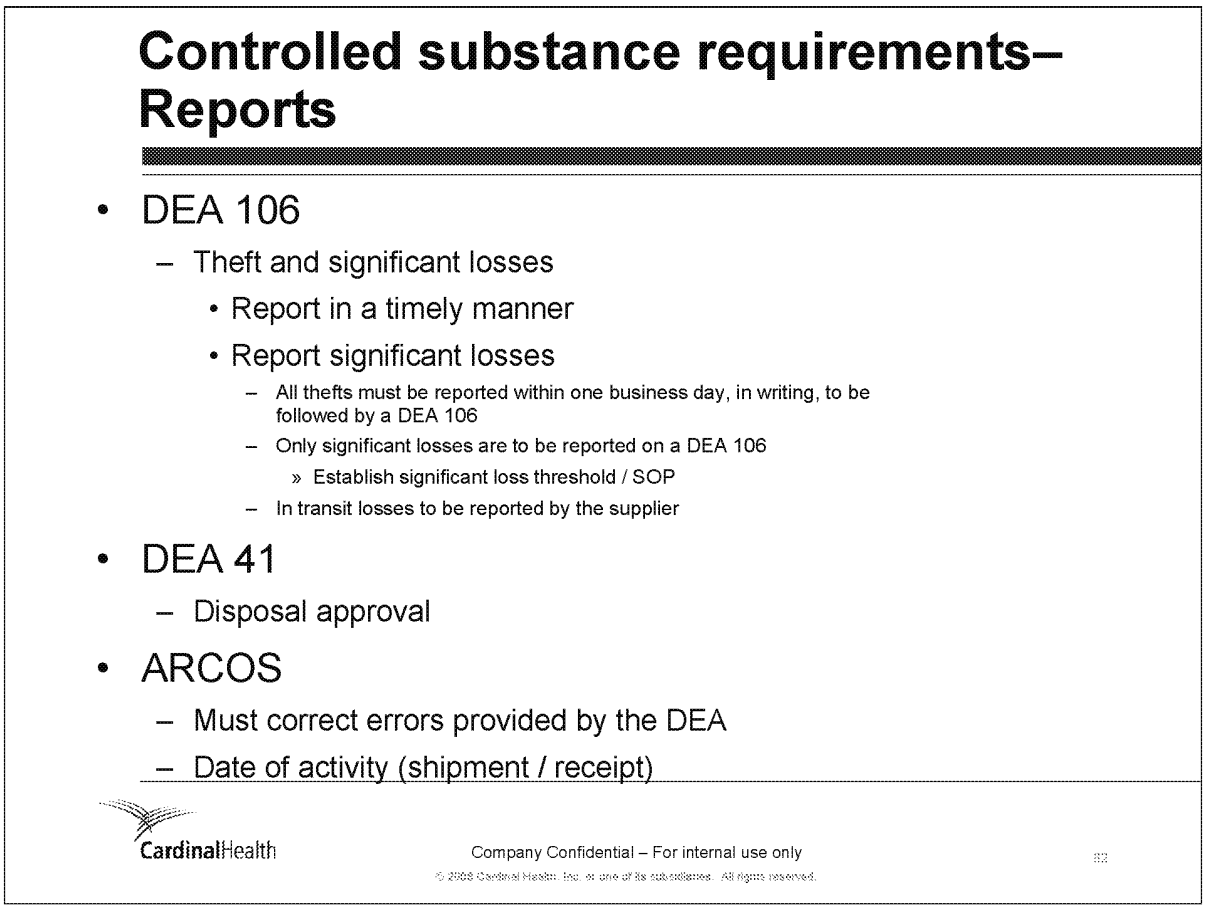
Notes:What are some of the potential points of diversion at the DC level?
Have people discuss at the table and ask for volunteers.
List on a flip chart. Then show rest of slide and discuss.



Objective: Discuss the record keeping requirements and potential failure areas

Timing: 5 min

Notes: These outline the record keeping requirements and the violations discovered by the DEA during their investigations of distribution centers. The regulations require that distribution centers maintain an executed DEA Form 222 for the receipt and distribution of a Schedule II and in addition to a DEA Form 222 for Schedule II, a receiving and distribution record is required for Schedule II, III, IV and V controlled substances. This record must list the name, address and DEA registration number of the customer / supplier, date of receipt / distribution, drug name, dosage form, strength, quantity and number of commercial containers.



Objective: Review the record keeping around theft – disposal – and inventory errors

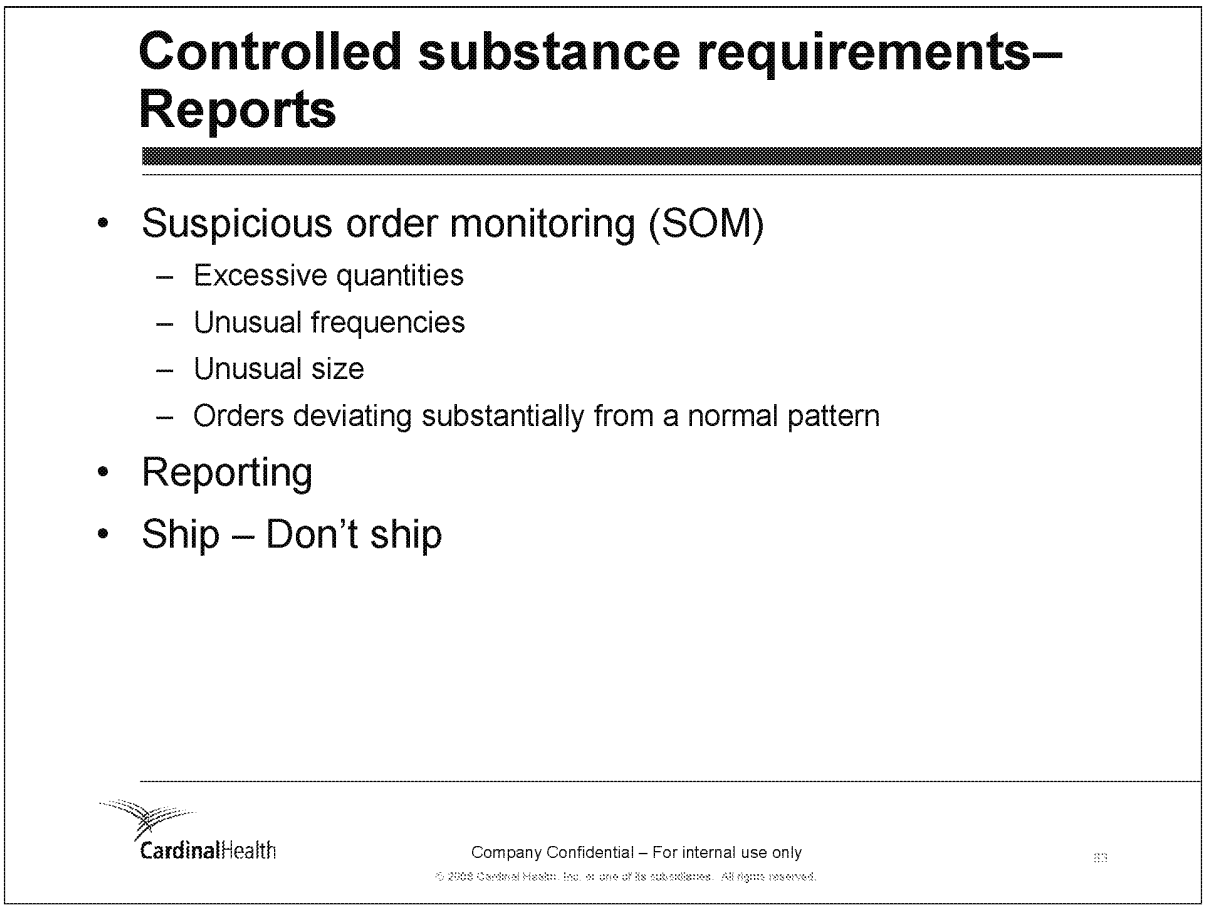
Timing: 3 min

Notes:
Give short explanation of each of these reports.
Automation of Reports and Consolidated Orders System
Discuss what is 'significant'. DEA does not define significant but as long as the threshold is consistent and reasonable (explainable) then that is acceptable by the agency.

Describe ARCOS and the level of authority to make changes in on hands. DEA is always looking for double checks in this regard to thwart internal diversion by record changing.

DEA has found that a number of registrants fail to report thefts and significant losses in a timely manner, dispose of drugs without following the regulatory requirements and fail to correct ARCOS errors. Discussions included these issues and the regulatory requirements for determining significant losses and reporting requirements; how to handle disposal of controlled substances and preventing and/or correcting ARCOS errors.

Transition: Keeping proper records is important to discourage the potential for diversion within the facility. Review of these records can also give more visibility to the potential of external diversion through orders. This is the internal component to Suspicious Order Monitoring. Because who's responsibility is antidiversion ?



Objective: Internal observation of potentially excessive orders

Timing: 3 min

Notes:
Suspicious Order Monitoring. What things might we be looking for? What behavior from an ordering standpoint could be considered suspicious?

Ask for comments then show.

Inventory and inventory adjustments

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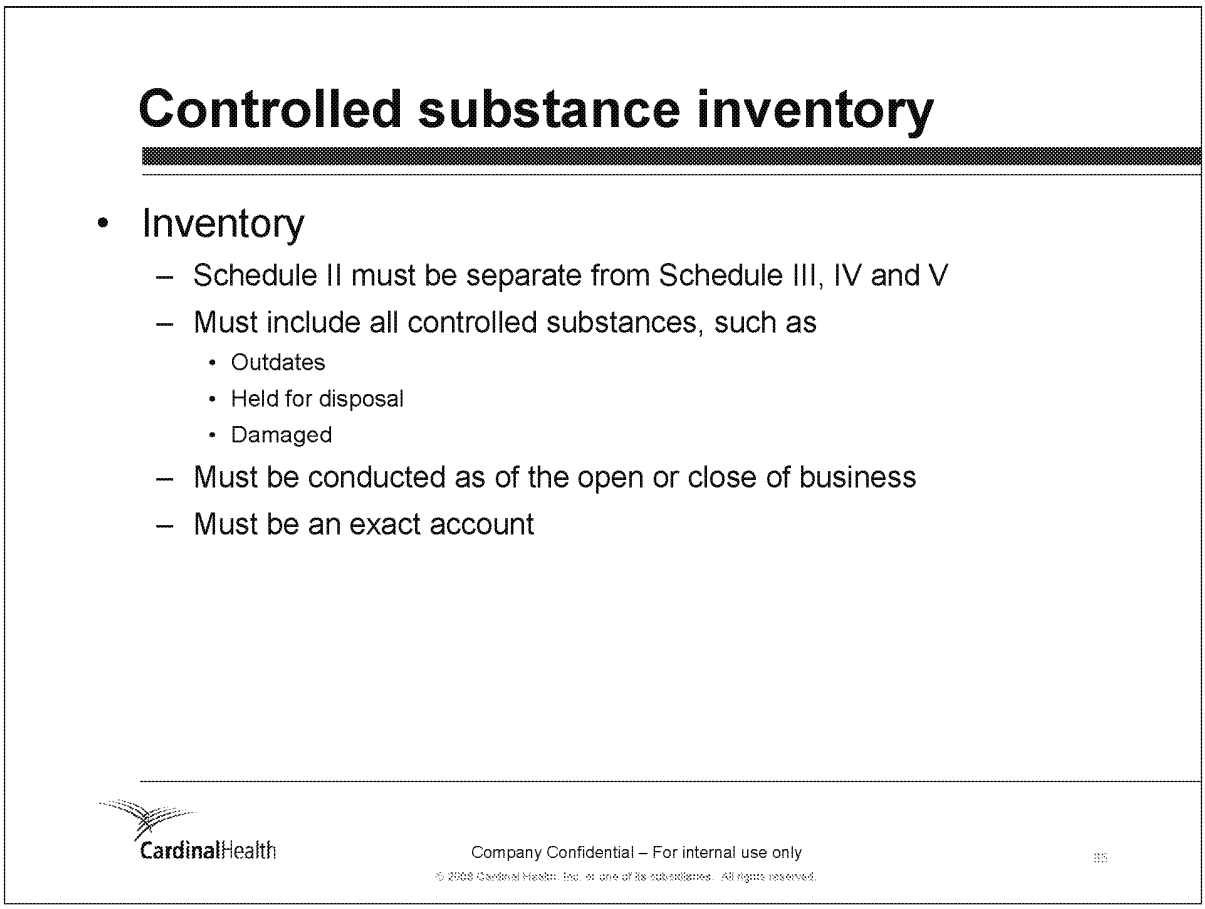
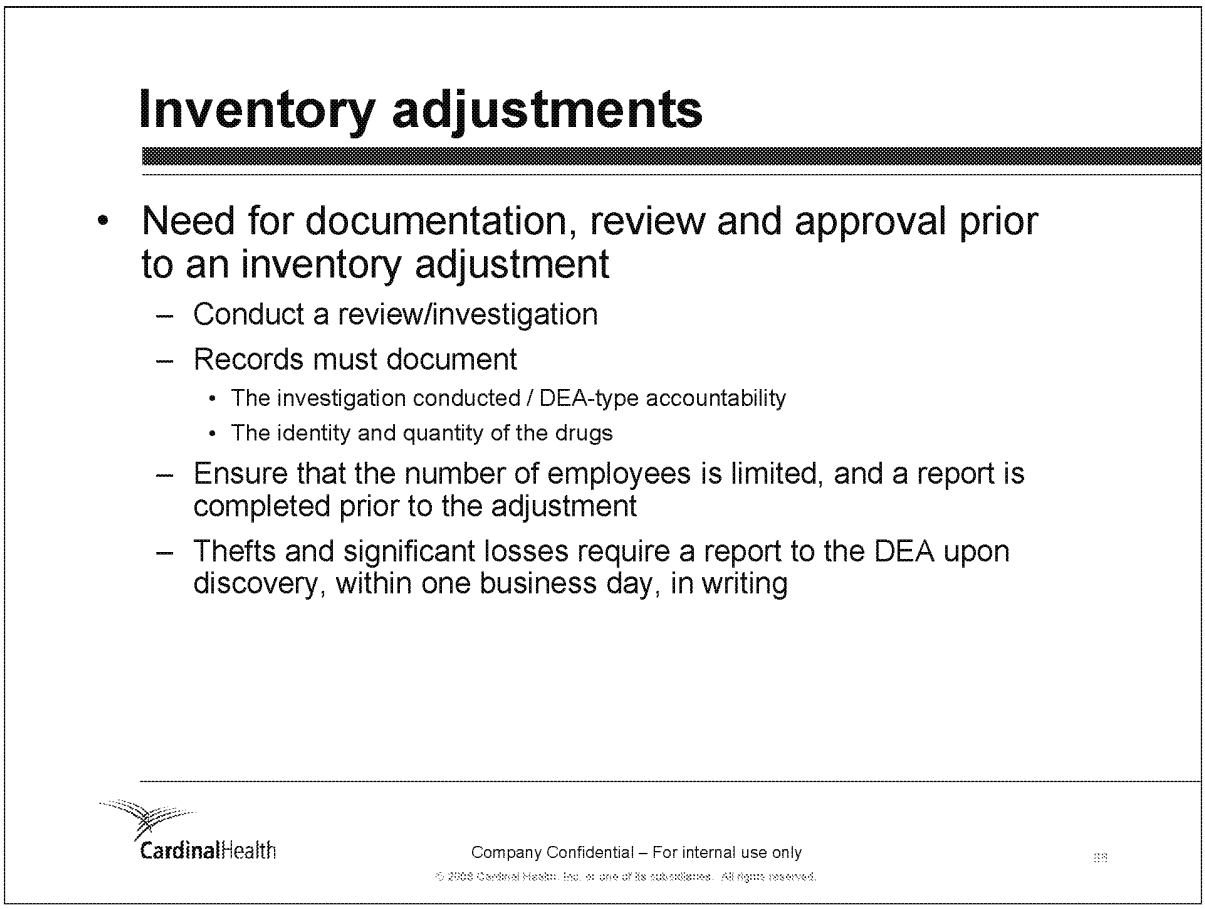


Objective: Review the requirements for physical inventory of controls and the potential violations

Timing: 3 min

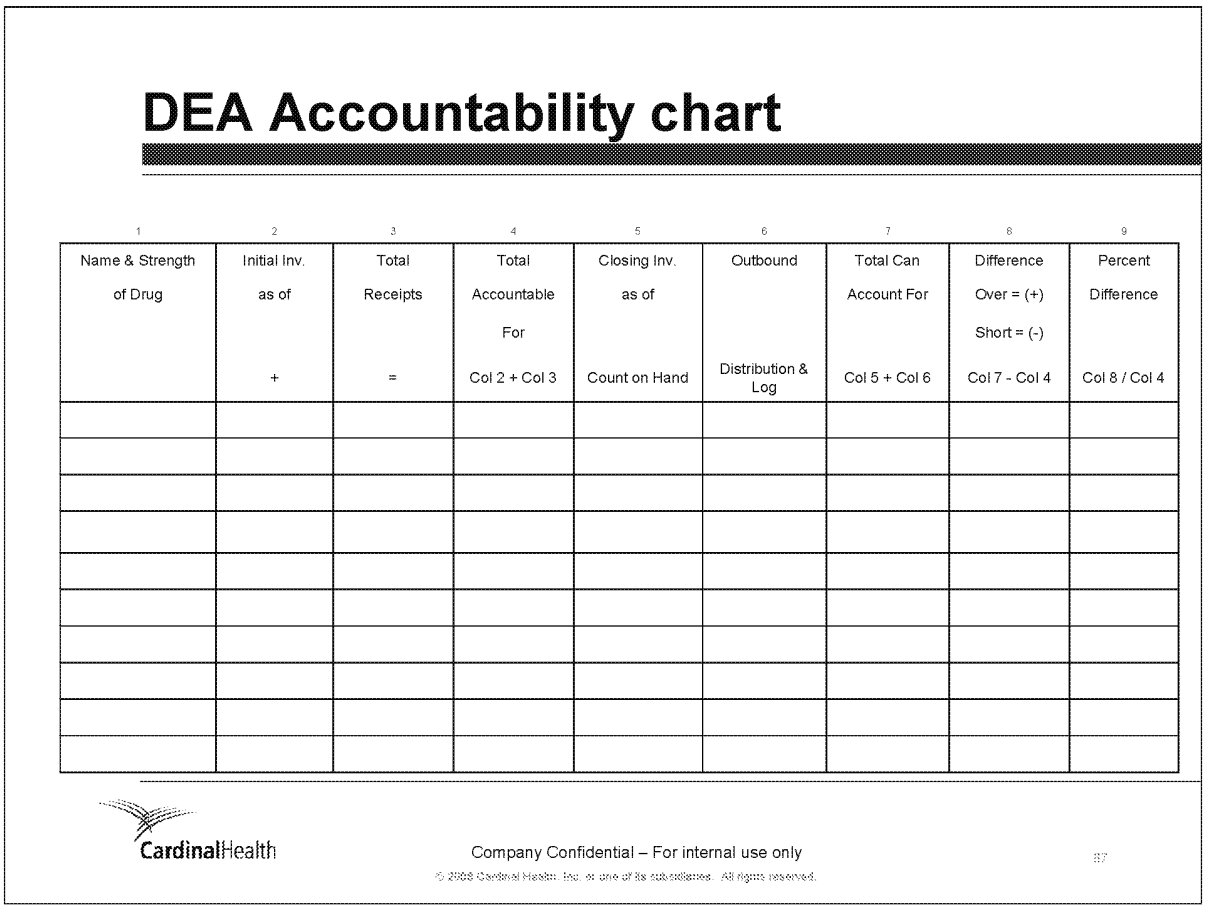
Notes:DEA has a requirement to conduct an accurate count inventory of all controlled substances in the possession and control of the DEA registered distribution center at a maximum of every two years and include if conducted at the opening or close of business, drug name, dosage form, strength, quantity and number of commercial containers. The slide discusses the inventory violations discovered by the DEA during their investigations.



Objective: Discuss Inventory adjustments

Timing: 5 min

Notes:DEA considers automatic inventory adjustments as a method for covering employee thefts. DEA requires and desires to see a documented method and justification prior to allowing an adjustment to inventories. DEA wants to see that a manager who doesn't control either the system and actual inventory approve any adjustments to the inventory.



DEA Accountability chart

1	2	3	4	5	6	7	8	9
Name & Strength of Drug	Initial Inv. as of +	Total Receipts =	Total Accountable For Col 2 + Col 3	Closing Inv. as of Count on Hand	Outbound Distribution & Log	Total Can Account For Col 5 + Col 6	Difference Over = (+) Short = (-) Col 7 - Col 4	Percent Difference Col 8 / Col 4

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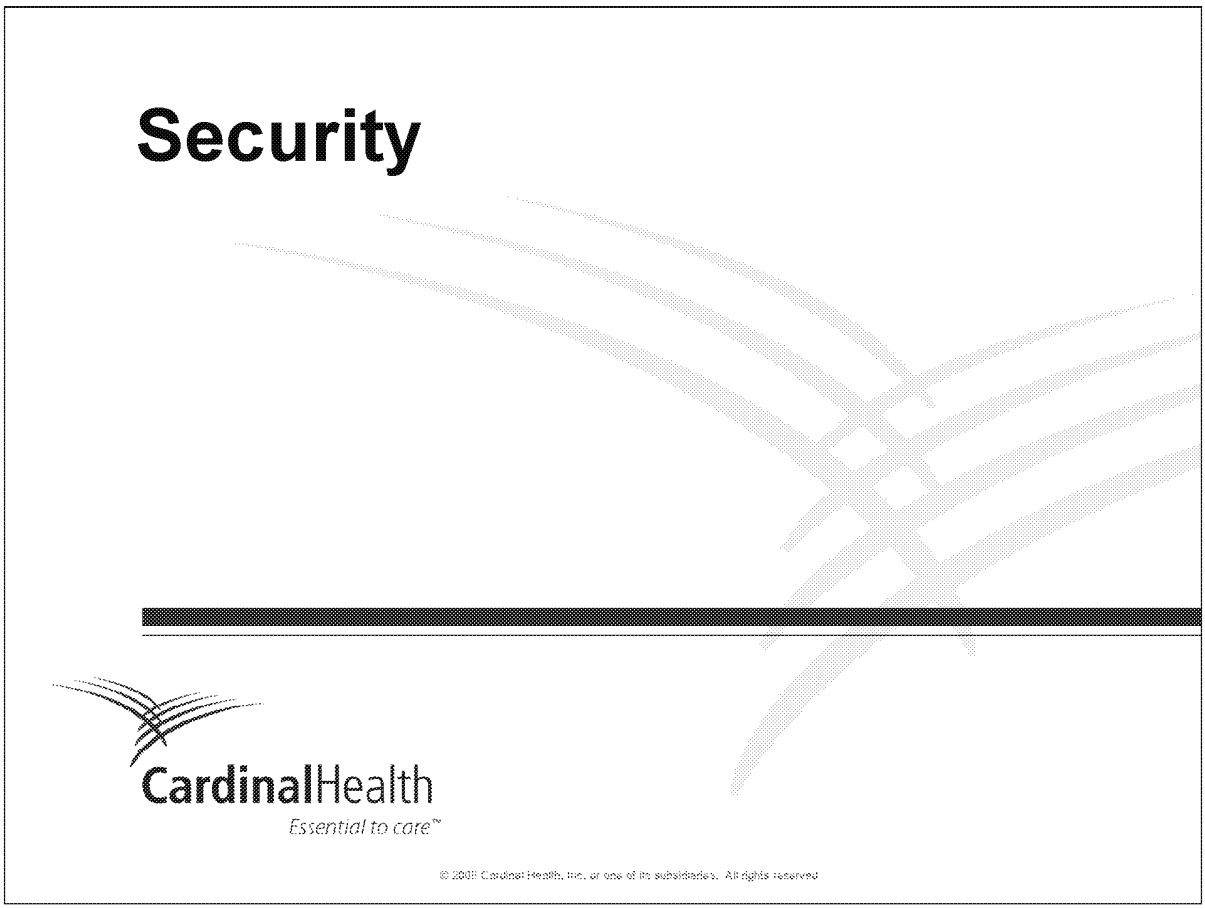
Objective: Accountability Chart is what DEA uses

Timing: 5 min

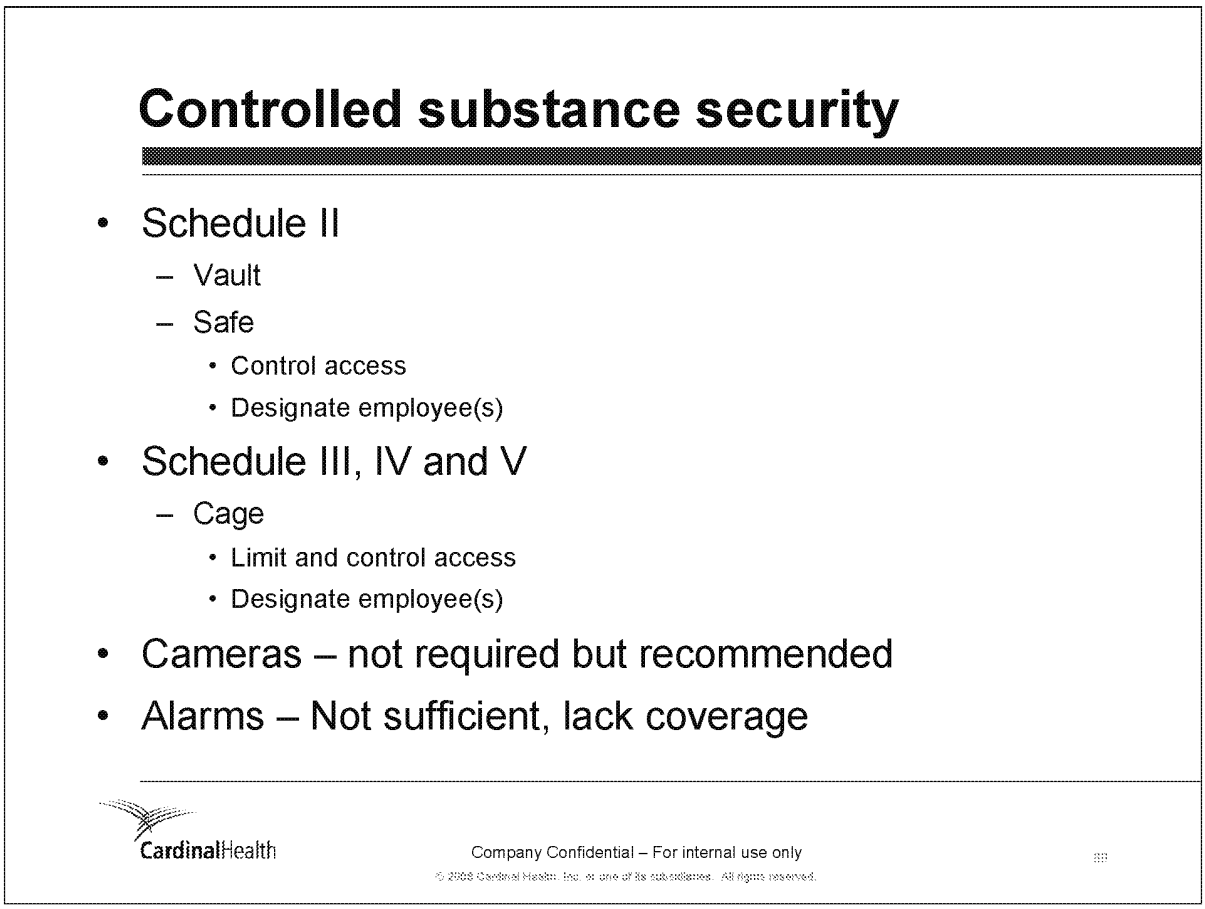
Notes:
Inventory amount should include all receipts, sales, damage, outdate, destroyed, lost.
Often violations occur because the record keeping did not include all of these components thereby making the inventory off.



Objective: Discuss physical security to prevent diversion

Timing: 1 min

Notes: Let's talk about how we keep the area's secure to discourage casual diversion



Objective: Relate the levels of security

Timing: 5 min

Notes:The regulations outline the security requirements for Schedule II and III, IV and V controlled substances. These requirements include vaults, cages, access controls, alarms, employee backgrounds, etc

Pharmacy dispensing

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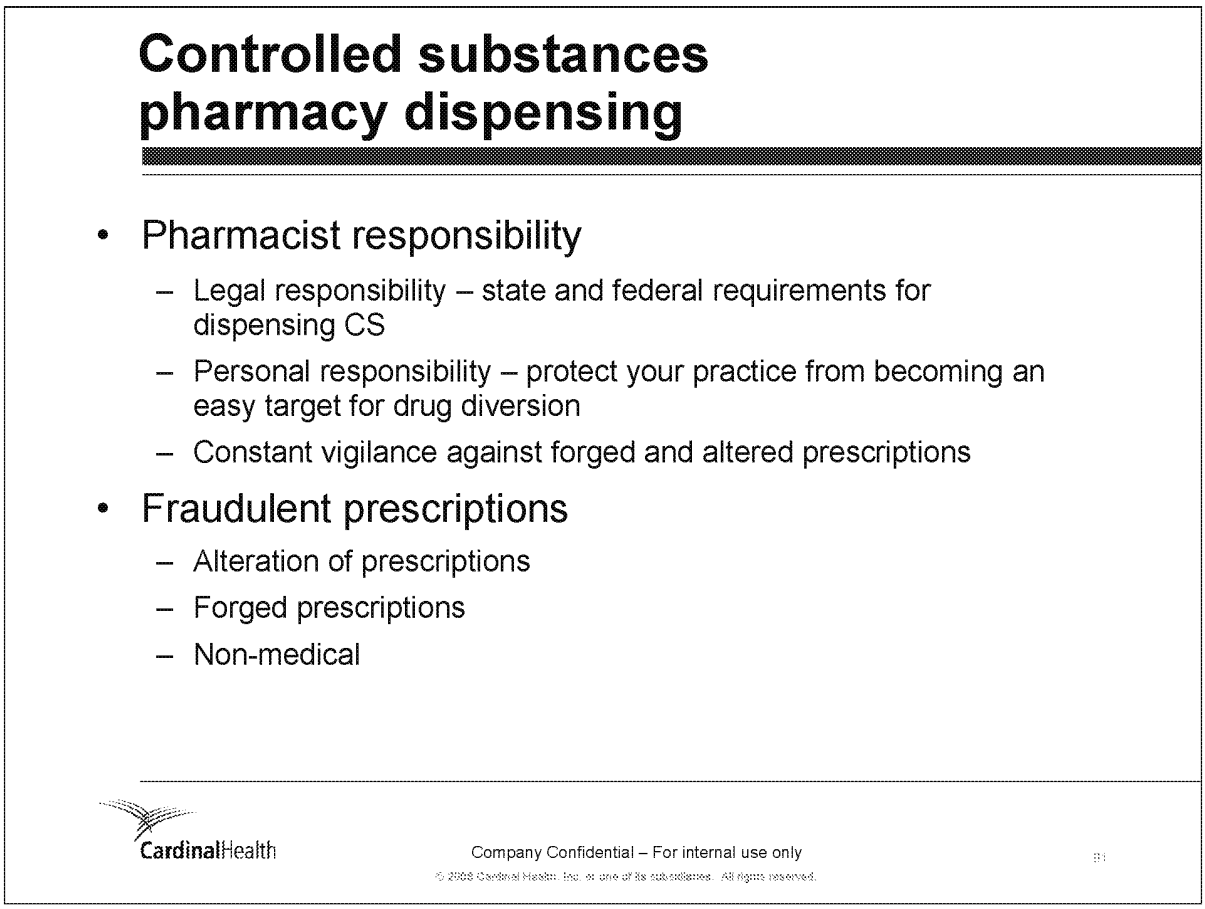
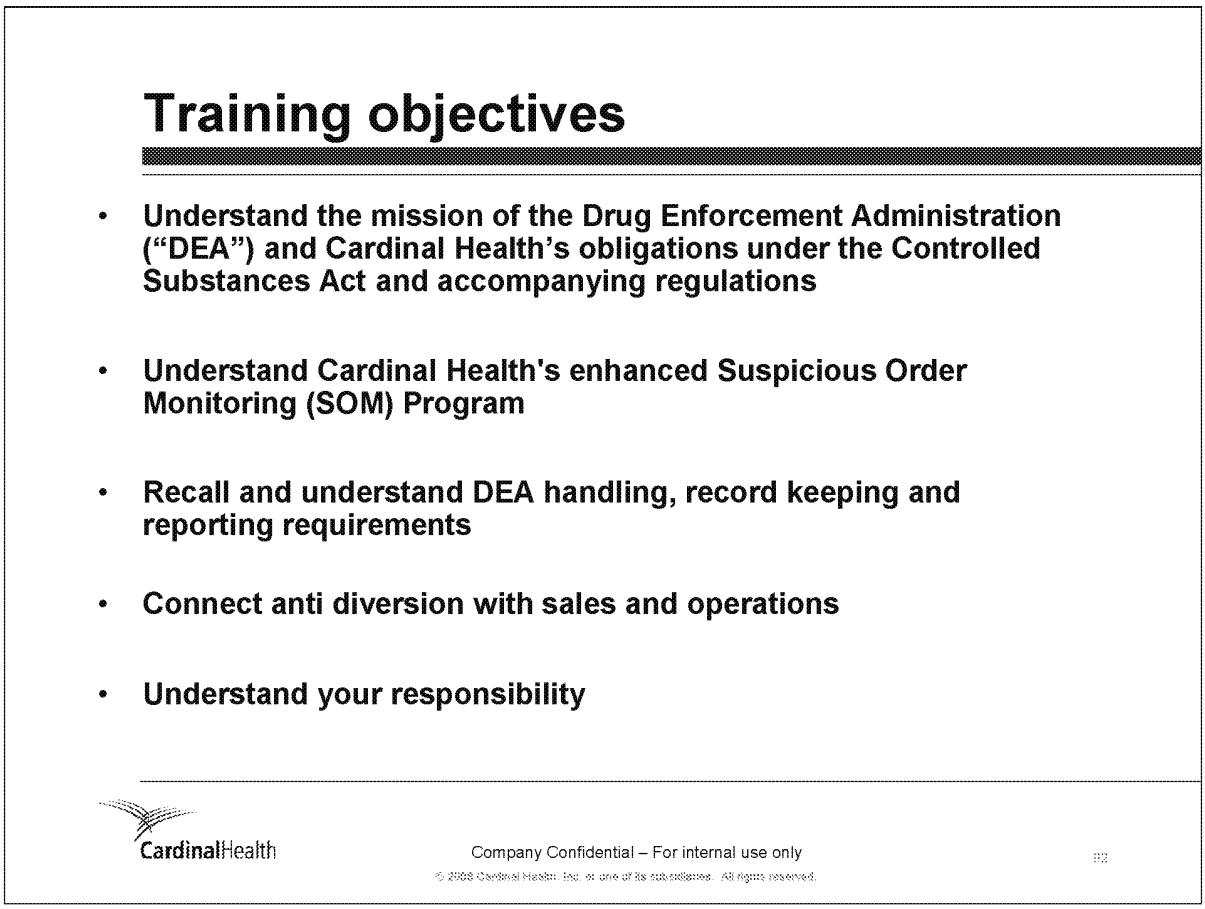


Objective: Relate pharmacy responsibility

Timing: 5 min

Notes: Pharmacy must be licensed with the state and federal government. They must also adhere to the regulations concerning controlled substances from both agencies.
This includes understanding what the doctor patient relationship is and to only fill prescriptions that meet that criteria
They must also be looking for forged or altered prescriptions.

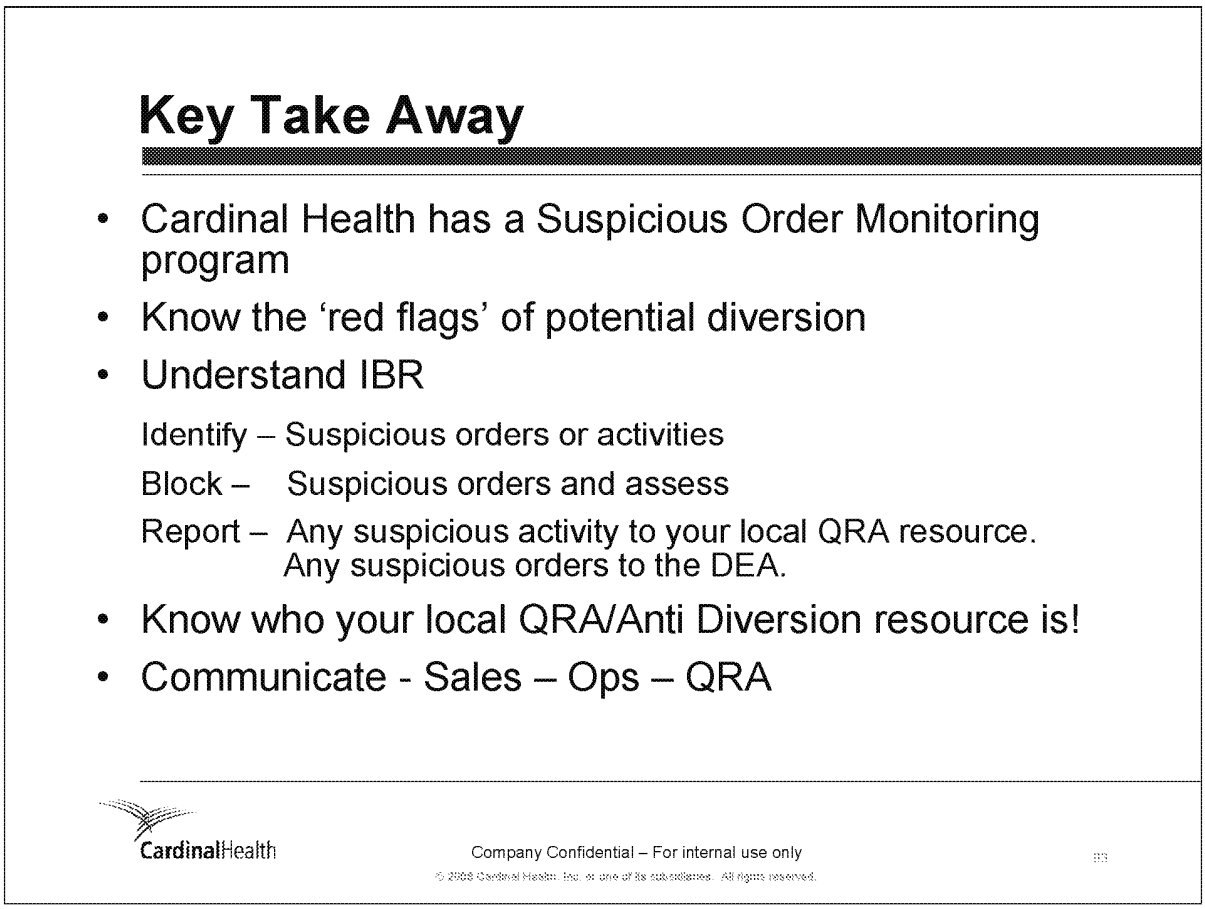
Transition: We have covered who's responsibility anti diversion is, we have talked about the red flags internally and externally
Let's look at our take aways.



Objective: Set the objectives

Timing: 2 min

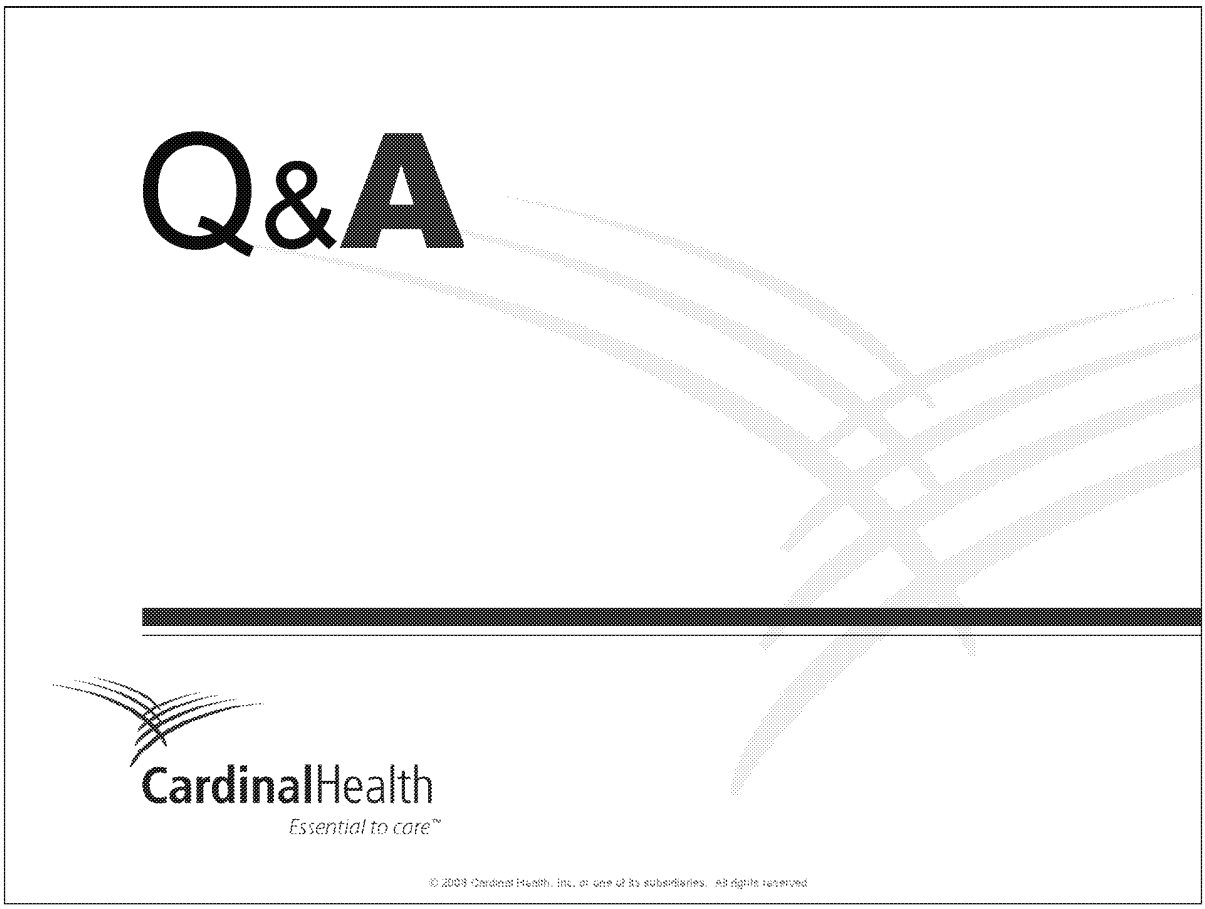
Notes Over the last few months we have made begun to focus even more on our anti diversion commitment. In order to make sure that we are consistent in our understanding of the process we have been tasked with sharing this training with you. Some things will be familiar to you. Our know your customer program is familiar to sales and some of the reporting and security processes are familiar to operations.
So what are we doing here today
Understand DEA mission
Understand Cardinal Health's enhanced SOM program
Recall handling and record keeping requirments
And finally to connect the antidiversion efforts of sales and operations to make a combined front against this societal problem.



Objective: Drive home take aways

Timing: 2 min

Notes Wrap up discussion with recap.
Covered the history of controlled substances and shift in abuse patterns
We discussed our importance in making sure we can do our part to keep society safe
We looked at our Suspicious Order Monitoring program with Michael Mone to see how that works and why
We have seen how critical our role is in resolving the anti diversion problem
These are the things you need to be familiar with as you do your job. At any given time you will want to be able to test yourself on your knowledge of these subjects.
We have a SOM program
We know the red flags
We understand IBR
We know our QRA resource
We communicate with each other.
This is how we will all make an impact.


Q&A
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Thank you!

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